# ABX Pentra 60 C+

User Manual
P/n: RAB092IEN

HAN 616A

HORIBA ABX
Diagnostics

# Instrument User Manual Update

RAM227AEN

## ABX Pentra 60 C+

## User Manual Update for Electrical Standard Certification

**Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.**

Date: 28/7/08

FORM 0860 - rev 1

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# Update chart

Tab.1-1: Concerned sections of the Pentra 60 C+ user manual:

| Section | Page | Paragraph | Item change |
|---|---|---|---|
| Front page | I | Manufacturer | Telephone and fax number addition.<br>See “1. Manufacturer, page 4” |
| Front page | I | Manufacturer | Modification of Manufacturer logo.<br>See “2. Logo modification, page 4” |
| Introduction | II | Copyright | Modification of Copyright.<br>See “3. Copyright, page 4” |
| Introduction | III | Revisions | Modification of paper documents updates.<br>See “4. Revisions, page 4” |
| Introduction | IV | 1.1. Warnings | Peripheral devices compliance sentence modification.<br>See “5. Warnings, page 4” |
| Introduction | VIII | 1.6. Graphics and Symbols | Modification of Manufacturer logo and addition of new RoHS logos.<br>See “6. Graphic and symbols, page 5” |
| Description & Technology | 2.3 | 1.2. Pentra 60 C+ back side | New Serial Number Label.<br>See “7. Pentra 60 C+ back side, page 5” |
| Specimen Run & Results | 3-2 | 1.1. Waste levels | Addition of precautions about waste.<br>See “8. Waste levels, page 6” |
| Specimen Run & Results | 3-34 | NE flag | Ne flag information.<br>See “9. NE flag, page 6” |
| Maintenance & Troubleshooting | 5.2 | 1.1. Reagent replacement | Addition of verification after reagent replacement.<br>See “10. Verification after a reagent replacement, page 6” |

# Updates

## 1. Manufacturer

Telephone and fax numbers:

- Phone: + 33 (0)4.67.14.15.16
- Fax: + 33 (0)4.67.14.15.17

## 2. Logo modification

New Manufacturer logo.

## 3. Copyright

Copyright 2008 HORIBA ABX SAS

## 4. Revisions

| Index | Technical note | Revision | Section | Date |
|---|---|---|---|---|
| A | RAH774AA | V1.50 | All | 26/06/200 |
| B | RAH792AA | V1.61 | All | 20/02/2001 |
| C | RAH873AA | V2.2 | ALL | 14/01/2002 |
| D | RAH986AA | V2.2.9 | All | 24/09/2003 |
| E | RAN179A | V2.3.0 (RAM146AEN) | 1, 3 | 16/11/2005 |
| RAB092FEN | / | Instrument default settings (RAM200AEN)<br>User manual update (RAM205AEN) | 4<br>Intro, 1, 2, 3 | 10/10/2006 |
| RAB092GEN | RAN321A | Platelet interferences (RAM210BEN)<br>V2.4.0 (RAM215AEN) | 2<br>3, 4, 5 | 08/06/2007 |
| RAB092HEN | RAN321B | V2.4.X (RAM215BEN) | 3, 4, 5 | 30/11/2007 |
| RAB092IEN | / | Electrical standard certification (RAM227AEN) | Intro, 2, 3, 5 | 21/05/2008 |

This document applies to the latest software listed and higher versions.
When a subsequent software version changes the information in this document, a new electronic issue (CD-ROM and/or online help) will be released and supplied by HORIBA ABX.
To update a paper document, please contact your local HORIBA ABX representative.

## 5. Warnings

- All peripheral devices should comply with relevant standards.

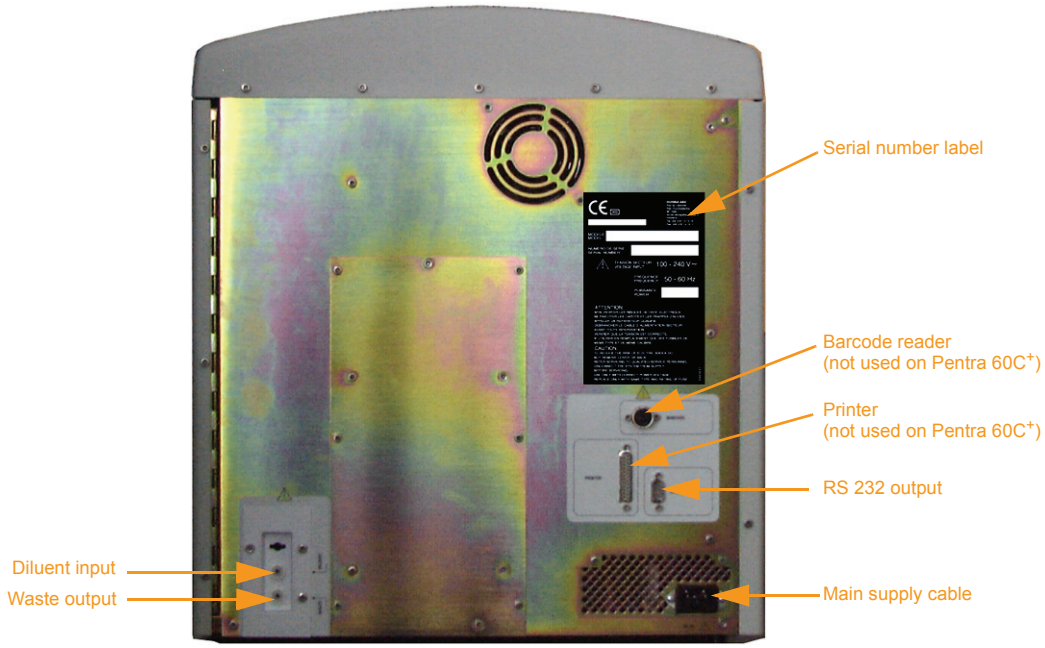
# 6. Graphic and symbols

Manufacturer

Packaging recycling mark

Notice of environment-friendly use period

# 7. Pentra 60 C+ back side




**Serial number label**

HORIBA ABX
Rue du Caducée
Parc Euromedecine
BP 7290
34184 Montpellier Cedex 4
FRANCE
Tél. (33) 4 67 14 15 16
Fax. (33) 4 67 14 15 17
MODELE
MODEL
NUMERO DE SERIE
SERIAL NUMBER
TENSION SECTEUR
VOLTAGE INPUT
100 - 240 V~
FREQUENCE
FREQUENCY
50 - 60 Hz
PUISSANCE
POWER
ATTENTION:
. AFIN D'EVITER LES RISQUES DE CHOC ELECTRIQUE
NE PAS OTER LES CAPOTS ET LES TRAPPES D'ACCES.
. APPELER UN REPARATEUR QUALIFIE.
. DEBRANCHER LE CABLE D'ALIMENTATION SECTEUR
AVANT TOUTE INTERVENTION.
. VERIFIER QUE LA TENSION EST CORRECTE.
. N'UTILISER EN REMPLACEMENT QUE DES FUSIBLES DE
MEME TYPE ET DE MEME CALIBRE.
CAUTION:
. TO REDUCE THE RISK OF ELECTRIC SHOCK DO
NOT REMOVE COVER OR BACK.
. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
. DISCONNECT THE SYSTEM FROM SUPPLY
BEFORE SERVICING.
. USE ONLY WITH CORRECT POWER VOLTAGE.
. REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.
HAX0231

# 8. Waste levels

**At the beginning of each day, before startup, check if the waste container needs to be emptied.**
**During the operation, do not remove the reagent tubes and the waste liquid tube under any condition.**

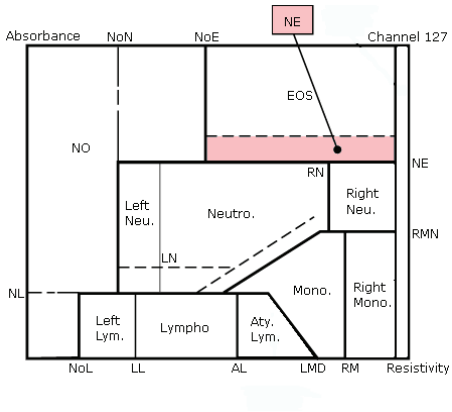
# 9. NE flag

Meaning: **N**eutro/**E**osino.
Presence of a significantly large population of cells located in the separation area between neutrophils and eosinophils because of a superimposition of the 2 populations. This flag occurs when the number of particles counted in this area is higher than the limit setup in **NE#** or when the number of particules counted regarding the total number of WBC is above the **NE%** limit.
**Standard** values for **NE**: % 1.1 / # *60*

Suspected abnormalities:

- Young eosinophils
- Giant hypersegmented neutrophils
- Eosinophils with low intracytoplasmic material
- Immature cells
- Neutrophils with cytotoxic granulations

This flag is associated with an (**!**) on LIC % and LIC # and replaces NEU %, NEU #, EOS %, EOS # by ----.




# 10. Verification after a reagent replacement

**Make sure that a blank cycle and Control run will be carried out after the change of a reagent in the course of day.**

HORIBA ABX
Diagnostics

# Instrument User Manual Update

## RAM215BEN

## ABX Pentra 60 C+

## Update for instrument version V2.4.X

**Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.**

Date: 30/11/07

FORM 0860 - rev 1

# Update for instrument version V2.4.X

Tab.1-1: Concerned sections of the manual

| Section | Page | Paragraph | Item change |
|---|---|---|---|
| Specimen run & Results | 3-24 | 7.4. Flags | Addition of paragraph “Suspicion flags” See “1. Suspicion flag, page 2” |
| Specimen run & Results | 3-45 | 7.5.3. Plt messages | Addition of message condition in “PLT Aggregate (1)” See “2. Plt messages, page 3” |
| Maintenance & Troubleshouting | 5-2 | 1.1. Reagent replacement | Addition of ABX Diluent 10L See “3. ABX Diluent 10L, page 3” |
| Instrument configuration | 4-2 | 1. Control | Addition of Export QC See “4. Export QC, page 3” |

**Index History:**

From RAM215AEN to RAM215BEN: V2.4.0 replaced by V2.4.X and modification of conditions on platelets.

# 1. Suspicion flag

## 1.1. PLT

| Conditions | Triggered flag | Consequences |
|---|---|---|
| If PLT < 120x10$^3$/mm$^3$ (in CBC mode only) | (!) on PLT and on PDW, MPV, PCT | PLT result needs to be confirmed according to Good Laboratory Working Practices |
| If PLT < 120x10$^3$/mm$^3$ + PDW > 20 (in CBC and DIFF mode) | | |

## 1.2. WBC

- If a flag LMNE+ or LMNE- or BASO+ is triggered, then a suspicion flag «!» on WBC parameter is generated too. See “7.4.7. WBC balance”.
- If a suspicion flag «!» on WBC occurs, then «!» is also generated on BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY%, LIC#, LIC% parameter results.
- A suspicion flag «!» is generated on the BAS#, BAS%, LYM#, LYM%, MON#, MON%, NEU#, NEU% and EOS#, EOS% parameter results if Hgb > 17,5 g/dl or invalid «---».

# 2. Plt messages

"H": high extreme limit
"L": low extreme limit

| Message | Triggering conditions |
|---|---|
| Thrombocytosis | PLT > PLT H |
| Thrombocytopenia | PLT < PLT L |
| Microcytosis<br>Schizocyte<br>Small Cell | See triggering conditions for these flags in paragraph "7.4.5.Flags on RBC histogram". |
| PLT Aggregate (1) | PLT < $150x10^3/mm^3$ + WBC Reject or<br>NO + PDW > 20 or<br>NO + MPV > 10 or<br>NO + PLT < $150x10^3/mm^3$ or<br>NO + WBC Reject or<br>(L1 or LL1) + PDW > 20 or<br>(L1 or LL1) + MPV > 10 or<br>(L1 or LL1) + PLT < $150x10^3/mm^3$<br>**PDW > 20 + PLT < $120x10^3/mm^3$ (in CBC mode only)*** |
| Erythroblasts(2) | LL or<br>WBC reject + L1 or<br>WBC reject + LL1 |
| Erythroblasts<br>PLT Aggregate | If conditions 1 and 2 are not satisfied<br>and if L1 or LL1 or WBC reject |
| Macroplatelets | MPV > 11 |

* New condition

# 3. ABX Diluent 10L

A 10 liters container of ABX Diluent is available under the part number: 0901010.

Software version v2.4.X introduces 10L or 20L volumes management (barcode identification, capacity, level, expiration date, etc.).

# 4. Export QC

Software version v2.4.X allows backup of QC results and statistics on floppy disk.
This backup file is registered on a «.csv» format in order to be reused on a spreadsheet type software.

## 4.1. Saved QC data

- Only one «.csv» file is generated for each control lot number.
- Each «.csv» file has a unique name and is generated in the current language and units. File name is saved on the following model : «xxx_AAAAMMJJ.csv» where xxx is the lot# and AAAAMMJJ the file creation date.

## 4.2. Limitations

RUO (for Research Use Only) parameters (PCT, PDW, ALY, LIC) are not saved on the Export QC file.

## 4.3. Export QC file content

Each file includes the following fields:

Header

- Instrument name / Lab ID
- Instrument serial number
- Lot number
- File creation date time
- Start period for lot use
- End period for lot use
- Expiration date
- Comment
- User lot comment
- Unit used

CBC data (Minotrol)

3 parts for Low, Normal and High levels

- Results detailed by parameters
- Statistics results
- lot target values

DIFF data (Difftrol)

3 parts for Low, Normal and High levels

- Results detailed by parameters
- Statistics results
- lot target values

See “Tab.1-1: DIF example” in the following page.

## 4.4. Procedure to export QC data

- Insert a Windows formatted Floppy disk into the drive.
- Open the «QC & Calibration» Tab (See “Fig.1-1: «QC & Calibration» tab, page 4”).
- Select the lot to export (Fig.1-1-A).
- Click the «Export QC» button (Fig.1-1-B).

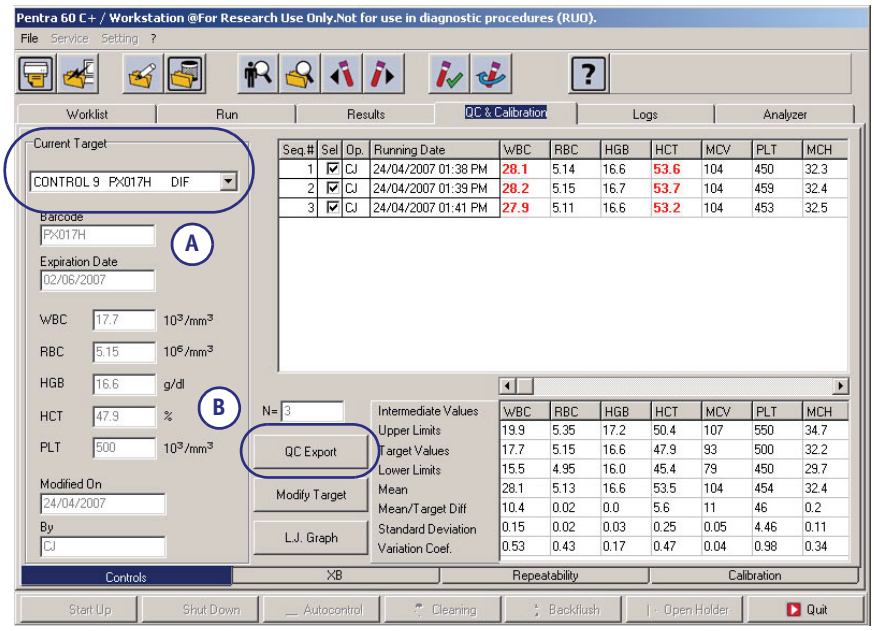

Pentra 60 C+ / Workstation @For Research Use Only.Not for use in diagnostic procedures (RUO).
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Current Target
CONTROL 9 PX017H DIF
Barcode
PX017H
A
Expiration Date
02/06/2007
WBC 17.7 10³/mm³
RBC 5.15 10⁶/mm³
HGB 16.6 g/dl
HCT 47.9 %
PLT 500 10³/mm³
B
Modified On
24/04/2007
By
CJ
N= 3
QC Export
Modify Target
L.J. Graph
Seq.# Sel Op. Running Date WBC RBC HGB HCT MCV PLT MCH
1 CJ 24/04/2007 01:38 PM 28.1 5.14 16.6 53.6 104 450 32.3
2 CJ 24/04/2007 01:39 PM 28.2 5.15 16.7 53.7 104 459 32.4
3 CJ 24/04/2007 01:41 PM 27.9 5.11 16.6 53.2 104 453 32.5
Intermediate Values WBC RBC HGB HCT MCV PLT MCH
Upper Limits 19.9 5.35 17.2 50.4 107 550 34.7
Target Values 17.7 5.15 16.6 47.9 93 500 32.2
Lower Limits 15.5 4.95 16.0 45.4 79 450 29.7
Mean 28.1 5.13 16.6 53.5 104 454 32.4
Mean/Target Diff 10.4 0.02 0.0 5.6 11 46 0.2
Standard Deviation 0.15 0.02 0.03 0.25 0.05 4.46 0.11
Variation Coef. 0.53 0.43 0.17 0.47 0.04 0.98 0.34
Controls XB Repeatability Calibration
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit

Fig.1-1: «QC & Calibration» tab

- Accept when the following message is displayed «Do you confirm QC export?»

- **The use of Export QC function will copy all levels results of the selected lot on the floppy disk at the same time.**
- **Lot barcode identification must not be modified to allow QC exportation on floppy disk.**
- **Statistical calculation results displayed in .csv file on the floppy disc are based on the raw values determined by the instrument, and not by the rounded values of control runs displayed in this .csv file.**

## Tab.1-1: DIF example

| | |
|---|---|
| Instrument name/Lab ID | Pentra60C+/ABX Parc Euro |
| Instrument serial number | 454548887 |
| Lot Number | PX017 |
| File creation date time | 04/24/2007 13:43 |
| Start period for lot use | |
| End period for lot use | |
| Expiration Date | 2/6/07 |
| Comment | Calculation results displayed on this floppy are based on the raw values determined by the instrument and not by the rounded value |
| User lot comment | |
| Unit used | STD |

DIF Difftrol

DIF Low

| Run date | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 04/24/2007 13:17 | 2.5 | | 2.48 | | 6.9 | | 22.7 | H | 92 | H | 27.7 | | 30.2 | L | 12.5 | | 46 | L | 4.8 | L | | | | | 24.1 | | 0.9 | | 57.7 | | 14.0 | | 3.3 | | | | | | 0.61 | | 0.02 | | 1.46 | | 0.35 | | 0.08 | | | | | |
| 04/24/2007 13:24 | 2.6 | | 2.50 | | 6.7 | | 22.9 | H | 91 | H | 26.7 | | 29.2 | L | 12.8 | | 56 | | 4.4 | L | | | | | 25.0 | | 0.7 | | 58.1 | | 12.9 | | 3.3 | | | | | | 0.64 | | 0.02 | | 1.49 | | 0.33 | | 0.08 | | | | | |
| 04/24/2007 13:26 | 2.5 | | 2.49 | | 6.8 | | 22.8 | H | 92 | H | 27.4 | | 29.9 | L | 13.0 | | 71 | | 4.3 | L | | | | | 24.8 | | 0.5 | | 55.9 | | 15.6 | | 3.2 | | | | | | 0.63 | | 0.01 | | 1.41 | | 0.39 | | 0.08 | | | | | |
| | WBC | | RBC | | HGB | | HCT | | MCV | | MCH | | MCHC | | RDW | | PLT | | MPV | | PCT | | PDW | | LYM% | | MON% | | NEU% | | EOS% | | BAS% | | ALY% | | LIC% | | LYM# | | MON# | | NEU# | | EOS# | | BAS# | | ALY# | | LIC# | |
| Lower limits | 2.0 | | 2.40 | | 6.3 | | 18.4 | | 75 | | 24.6 | | 30.7 | | 10.0 | | 46 | | 6.7 | | | | | | 19.0 | | --- | | 48.0 | | 3.0 | | 1.5 | | | | | | 0.43 | | --- | | 1.12 | | 0.04 | | 0.03 | | | | | |
| Target values | 2.4 | | 2.52 | | 6.7 | | 19.9 | | 79 | | 26.6 | | 33.7 | | 14.0 | | 66 | | 8.7 | | | | | | 27.0 | | 1.5 | | 58.0 | | 10.0 | | 3.5 | | | | | | 0.65 | | 0.04 | | 1.39 | | 0.24 | | 0.08 | | | | | |
| Upper limits | 2.8 | | 2.64 | | 7.1 | | 21.4 | | 83 | | 28.6 | | 36.7 | | 18.0 | | 86 | | 10.7 | | | | | | 35.0 | | 3.0 | | 68.0 | | 17.0 | | 5.5 | | | | | | 0.87 | | 0.08 | | 1.66 | | 0.44 | | 0.13 | | | | | |
| | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
| Mean | 2.5 | | 2.49 | | 6.8 | | 22.8 | | 92 | | 27.3 | | 29.8 | | 12.8 | | 57 | | 4.5 | | | | | | 24.6 | | 0.7 | | 57.2 | | 14.2 | | 3.3 | | | | | | 0.63 | | 0.02 | | 1.45 | | 0.36 | | 0.08 | | | | | |
| Mean/target diff. | 0.1 | | 0.03 | | 0.1 | | 2.9 | | 13 | | 0.7 | | 3.9 | | 1.2 | | 9 | | 4.2 | | | | | | 2.4 | | 0.8 | | 0.8 | | 4.2 | | 0.2 | | | | | | 0.02 | | 0.02 | | 0.06 | | 0.12 | | 0.00 | | | | | |
| Standard deviation | 0.02 | | 0.01 | | 0.1 | | 0.07 | | 0.07 | | 0.49 | | 0.52 | | 0.27 | | 12.72 | | 0.27 | | | | | | 0.47 | | 0.2 | | 1.17 | | 1.36 | | 0.06 | | | | | | 0.01 | | 0.01 | | 0.04 | | 0.03 | | 0.00 | | | | | |
| Variation Coeff. | 0.65 | | 0.37 | | 1.46 | | 0.29 | | 0.08 | | 1.81 | | 1.74 | | 2.08 | | 22.17 | H | 5.92 | | | | | | 1.92 | | 28.57 | | 2.05 | | 9.58 | | 1.77 | | | | | | 2.26 | | 28.67 | | 2.62 | | 8.97 | | 2.29 | | | | | |

DIF Normal

| Run date | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 04/24/2007 13:10 | 8.0 | | 4.44 | L | 13.2 | L | 44.5 | H | 100 | H | 29.7 | | 29.7 | L | 11.4 | | 229 | | 4.1 | L | | | | | 25.9 | | 0.6 | | 64.8 | | 5.5 | | 3.2 | H | | | | | 2.08 | | 0.05 | | 5.21 | | 0.44 | | 0.26 | | | | | |
| 04/24/2007 13:12 | 7.3 | | 4.35 | L | 13.4 | L | 43.7 | H | 100 | H | 30.9 | | 30.8 | L | 11.8 | | 218 | | 4.1 | L | | | | | 27.3 | | 0.6 | | 63.4 | | 5.3 | | 3.4 | H | | | | | 2.00 | | 0.04 | | 4.65 | | 0.39 | | 0.25 | | | | | |
| 04/24/2007 13:13 | 7.2 | | 4.41 | L | 13.4 | L | 44.3 | H | 101 | H | 30.5 | | 30.3 | L | 11.3 | | 219 | | 4.1 | L | | | | | 25.2 | | 0.6 | | 65.6 | | 5.3 | | 3.3 | H | | | | | 1.81 | | 0.04 | | 4.70 | | 0.38 | | 0.24 | | | | | |
| | WBC | | RBC | | HGB | | HCT | | MCV | | MCH | | MCHC | | RDW | | PLT | | MPV | | PCT | | PDW | | LYM% | | MON% | | NEU% | | EOS% | | BAS% | | ALY% | | LIC% | | LYM# | | MON# | | NEU# | | EOS# | | BAS# | | ALY# | | LIC# | |
| Lower limits | 6.3 | | 4.54 | | 13.5 | | 38.8 | | 83 | | 27.9 | | 31.3 | | 8.5 | | 205 | | 6.2 | | | | | | 20.5 | | --- | | 53.0 | | --- | | 0.0 | | | | | | 1.45 | | --- | | 3.82 | | --- | | 0.04 | | | | | |
| Target values | 7.3 | | 4.69 | | 14.0 | | 40.8 | | 87 | | 29.9 | | 34.3 | | 12.5 | | 235 | | 8.2 | | | | | | 28.5 | | 1.5 | | 63.0 | | 3.5 | | 0.3 | | | | | | 2.08 | | 0.11 | | 4.60 | | 0.26 | | 0.26 | | | | | |
| Upper limits | 8.3 | | 4.84 | | 14.5 | | 42.8 | | 91 | | 31.9 | | 37.3 | | 16.5 | | 265 | | 10.2 | | | | | | 36.5 | | 3.0 | | 73.0 | | 7.0 | | 0.5 | | | | | | 2.71 | | 0.22 | | 5.38 | | 0.52 | | 0.48 | | | | | |
| | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
| Mean | 7.5 | | 4.40 | | 13.4 | | 44.1 | | 100 | | 30.4 | | 30.3 | | 11.5 | | 222 | | 4.1 | | | | | | 26.1 | | 0.6 | | 64.6 | | 5.4 | | 3.3 | | | | | | 1.96 | | 0.05 | | 4.85 | | 0.40 | | 0.25 | | | | | |
| Mean/target diff. | 0.2 | | 0.29 | | 0.6 | | 3.3 | | 13 | | 0.5 | | 4.0 | | 1.0 | | 13 | | 4.1 | | | | | | 2.4 | | 0.9 | | 1.6 | | 1.9 | | 3.0 | | | | | | 0.12 | | 0.06 | | 0.25 | | 0.14 | | 0.01 | | | | | |
| Standard deviation | 0.46 | | 0.05 | | 0.13 | | 0.44 | | 0.2 | | 0.61 | | 0.56 | | 0.25 | | 6.04 | | --- | | | | | | 1.07 | | --- | | 1.11 | | 0.12 | | 0.1 | | | | | | 0.14 | | 0.00 | | 0.31 | | 0.03 | | 0.01 | | | | | |
| Variation Coeff. | 6.18 | | 1.09 | | 1.01 | | 0.99 | | 0.2 | | 2.0 | | 1.86 | | 2.19 | | 2.72 | | --- | | | | | | 4.09 | | --- | | 1.72 | | 2.15 | | 3.03 | | | | | | 7.24 | | 6.18 | | 6.4 | | 8.38 | | 4.24 | | | | | |

DIF High

| Run date | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 04/24/2007 13:38 | 28.1 | H | 5.14 | | 16.6 | | 53.6 | H | 104 | | 32.3 | | 31.0 | L | 10.3 | | 450 | | 3.8 | L | | | | | 13.8 | | 1.1 | | 75.4 | | 5.5 | | 4.2 | | | | | | 3.88 | | 0.31 | | 21.21 | H | 1.55 | | 1.18 | | | | | |
| 04/24/2007 13:39 | 28.2 | H | 5.15 | | 16.7 | | 53.7 | H | 104 | | 32.4 | | 31.0 | L | 10.7 | | 459 | | 3.7 | L | | | | | 13.7 | | 1.1 | | 76.0 | | 5.0 | | 4.2 | | | | | | 3.86 | | 0.31 | | 21.41 | H | 1.41 | | 1.18 | | | | | |
| 04/24/2007 13:41 | 27.9 | H | 5.11 | | 16.6 | | 53.2 | H | 104 | | 32.5 | | 31.2 | L | 10.5 | | 453 | | 3.8 | L | | | | | 13.5 | | 1.3 | | 75.5 | | 5.5 | | 4.2 | | | | | | 3.77 | | 0.36 | | 21.06 | H | 1.53 | | 1.17 | | | | | |
| | WBC | | RBC | | HGB | | HCT | | MCV | | MCH | | MCHC | | RDW | | PLT | | MPV | | PCT | | PDW | | LYM% | | | | NEU% | | EOS% | | BAS% | | ALY% | | LIC% | | LYM# | | MON# | | NEU# | | EOS# | | BAS# | | ALY# | | LIC# | |
| Lower limits | 15.5 | | 4.95 | | 16.0 | | 45.4 | | 79 | | 29.7 | | 31.7 | | 7.8 | | 450 | | 5.3 | | | | | | 5.5 | | MON% | | 65.5 | | 1.0 | | 1.0 | | | | | | 1.09 | | --- | | 11.56 | | 0.17 | | 0.13 | | | | | |
| Target values | 17.7 | | 5.15 | | 16.6 | | 47.9 | | 93 | | 32.2 | | 34.7 | | 11.8 | | 500 | | 7.3 | | | | | | 13.5 | | --- | | 75.5 | | 5.5 | | 4.0 | | | | | | 2.69 | | 0.27 | | 13.36 | | 0.97 | | 0.71 | | | | | |
| Upper limits | 19.9 | | 5.35 | | 17.2 | | 50.4 | | 107 | | 34.7 | | 37.7 | | 15.8 | | 550 | | 9.3 | | | | | | 21.5 | | 1.5 | | 85.5 | | 10.0 | | 7.0 | | | | | | 4.29 | | 0.54 | | 15.16 | | 1.77 | | 1.29 | | | | | |
| | WBC | WBC alarm | RBC | RBC alarm | HGB | HGB alarm | HCT | HCT alarm | MCV | MCV alarm | MCH | MCH alarm | MCHC | MCHC alarm | RDW | RDW alarm | PLT | PLT alarm | MPV | MPV alarm | PCT | PCT alarm | PDW | PDW alarm | LYM% | LYM% alarm | MON% | MON% alarm | NEU% | NEU% alarm | EOS% | EOS% alarm | BAS% | BAS% alarm | ALY% | ALY% alarm | LIC% | LIC% alarm | LYM# | LYM# alarm | MON# | MON# alarm | NEU# | NEU# alarm | EOS# | EOS# alarm | BAS# | BAS# alarm | ALY# | ALY# alarm | LIC# | LIC# alarm |
| Mean | 28.1 | | 5.13 | | 16.6 | | 53.5 | | 104 | | 32.4 | | 31.1 | | 10.5 | | 454 | | 3.8 | | | | | | 13.7 | | 1.2 | | 75.6 | | 5.3 | | 4.2 | | | | | | 3.84 | | 0.33 | | 21.23 | | 1.50 | | 1.18 | | | | | |
| Mean/target diff. | 10.4 | | 0.02 | | 0.0 | | 5.6 | | 11 | | 0.2 | | 3.6 | | 1.3 | | 46 | | 3.5 | | | | | | 0.2 | | 0.3 | | 0.1 | | 0.2 | | 0.2 | | | | | | 1.15 | | 0.06 | | 7.87 | | 0.53 | | 0.47 | | | | | |
| Standard deviation | 0.15 | | 0.02 | | 0.03 | | 0.25 | | 0.05 | | 0.11 | | 0.12 | | 0.17 | | 4.46 | | 0.04 | | | | | | 0.15 | | 0.12 | | 0.32 | | 0.29 | | --- | | | | | | 0.06 | | 0.03 | | 0.18 | | 0.08 | | 0.01 | | | | | |
| Variation Coeff. | 0.53 | | 0.43 | | 0.17 | | 0.47 | | 0.04 | | 0.34 | | 0.38 | | 1.62 | | 0.98 | | 0.98 | | | | | | 1.12 | | 9.9 | | 0.43 | | 5.41 | | --- | | | | | | 1.61 | | 9.34 | | 0.83 | | 5.12 | | 0.53 | | | | | |

HORIBA ABX
Diagnostics

# Instrument User Manual Update

## RAM210BEN

## ABX Pentra 60/60 C+
## Platelet interferences

**Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.**

Date: 6/4/07

FORM 0860 - rev 1

# Platelet interferences

## 1. ABX Pentra 60

Tab.1-1: Concerned sections of the manual

| Section | Paragraph | Item change |
|---|---|---|
| Specifications | 5.3. Known interfering substances | Modification of information about interference in the platelet results See "1.1. Plt (Platelets), page 2" |

### 1.1. Plt (Platelets)

- **Elevated lipids and/or cholesterol**: may interfere with correct platelet counting.
  From patients undergoing parenteral treatment with intralipids brought, it is noted an over-estimate of the platelet counting which can mask a thrombopenia in DIFF mode. In this case, sample re-run should be done in CBC mode.

- **Elevated bilirubine** : may interfere with correct platelet counting.
  From patients with severe hepatic disorder, liver transplant...It is noted an over-estimate of the platelet counting which can mask a thrombopenia.

## 2. ABX Pentra 60 C+

Tab.1-2: Concerned sections of the manual

| Section | Paragraph | Item change |
|---|---|---|
| Specifications | 5.3. Known interfering substances | Modification of information about interference in the platelet results See "2.1. Plt (Platelets), page 2" |

### 2.1. Plt (Platelets)

- **Elevated lipids and/or cholesterol**: may interfere with correct platelet counting.
  From patients undergoing parenteral treatment with intralipids brought, it is noted an over-estimate of the platelet counting which can mask a thrombopenia in DIFF mode. In this case, sample re-run should be done in CBC mode.

- **Elevated bilirubine** : may interfere with correct platelet counting.
  From patients with severe hepatic disorder, liver transplant...It is noted an over-estimate of the platelet counting which can mask a thrombopenia.

HORIBA ABX
Diagnostics

# Instrument User Manual Update

## RAM205AEN

## ABX Pentra 60 C+
## User manual update

**Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.**

Date: 10/10/06

FORM 0860 - rev 1

# User manual update

Tab.1-1: Concerned sections of the manual

| Section | Page | Paragraph | Item change |
|---|---|---|---|
| Introduction | II | Notice of liability | Paragraph correction<br>See “1. Notice of liability, page 3” |
| Introduction | III | Revisions | Addition of internet link to Declaration of conformity<br>See “2. Declaration of conformity, page 3” |
| Introduction | VI | 1.4. Biological risks | Recommendations addition<br>See “3. Biological risks, page 3” |
| Introduction | VIII | 1.6. Graphics and symbols | WEEE Directive symbol addition<br>See “4. Graphics and symbols, page 3” |
| Introduction | IX | 2.1. Environment | “Safety requirements” Standard evolution<br>See “5. Environment, page 3” |
| Introduction | X | 2.6. Environment protection | WEEE Directive addition<br>See “6. Environment protection, page 3” |
| Specifications | 1-6 | 2.1. Power requirements | Heat output addition<br>See “7. Power requirements, page 3” |
| Specifications | 1-8 | 2. Physical specifications | Addition of “2.9. Compatible tube list” paragraph<br>See “8. Compatible tube list, page 4” |
| Specifications | 1-15 | 4.1. Reagent specifications | A.F.S.S.A.P.S reference deletion and Reagent leaflets update<br>See “9. Reagent specifications, page 6” |
| Specifications | 1-17 | 5.3. Known interfering substances | Modification of known interferences due to Chemotherapy<br>See “10.1. White Blood Cells (Leukocytes), page 6” |
| Specifications | 1-19 | 5.3. Known interfering substances | Modification of interference in the platelet result information<br>See “10.2. Plt (Platelets), page 6” |
| Specifications | 1-20 | 5.3. Known interfering substances | Addition of interferences in the basophil count information<br>See “10.3. BAS# (Basophil cell count absolute), BAS% (Basophil percentage), page 6” |
| Description & Technology | 2-11 | 2.3. Hgb measurement | Addition of measuring principle with Lysebio<br>See “11. Hgb measurement, page 7” |
| Specimen run & Results | 3-5 | 3. Calibration verification (control blood sampling) | Addition of calibration general information See “12. Calibration verification (control blood sampling), page 7” |
| Specimen run & Results | 3-14 | 6. Running specimen | Addition of recommendations on the analysis mode selection<br>See “13. Running specimen, page 8” |
| Specimen run & Results | 3-39 | 7.4.4. Flags on WBC/BASO histogram | Addition of recommendations on CBC mode: L1 flag<br>See “14. Flags on WBC/BASO histogram, page 8” |
| Specimen run & Results | 3-43 | 7.4.7. WBC balance | Addition of CBC mode limitations<br>See “15. WBC balance, page 8” |

# 1. Notice of liability

The Information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, HORIBA ABX will not assume any liability to any persons or entities with respect to loss or damage, caused or alleged to be caused directly or indirectly by not following the instructions contained in this manual, or by using the computer software and hardware products described herein in a manner inconsistent with our product labeling.

# 2. Declaration of conformity

Latest version of the CE declaration of conformity for this instrument is available on www.horiba-abx.com.

# 3. Biological risks

**Consider all instrument accessible surfaces as potentially contaminated with blood.**
**Use protective gloves to operate instrument.**

# 4. Graphics and symbols

This product should be disposed of and recycled at the end of the useful life in accordance with the WEEE Directive (2002/96/CE)

# 5. Environment

The instrument is designed for safety from voltages surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1).

# 6. Environment protection

- **European Legislation:**

In accordance with the European Directive (2002/96/CE, known also as W.E.E.E) instruments having the above symbol, and sold into a European country by HORIBA ABX or an authorised representative must disposed of and recycled correctly at the end of its useful life.
Due to the local changing regulations in each country, please contact your local representative for detailed and upto date information on how to appropriately dispose of the instrument.

# 7. Power requirements

- Heat output..... ..... Max 1440 Kjoules/h (1365 BTU/h)

# 8. Compatible tube list

## 8.1. Compatible tube list for Tube holder

**Tube lists given in the tables below are not exhaustive. If the tubes in use in your laboratory does not match with this lists, please contact your HORIBA ABX service representative.**

**On microsampling tubes, the 100µl volume can only be use in the following conditions:**
**- The tube must be held always in vertical position**
**- Blood mixing must be obtained by slight tapping on the tube**
**Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.**

◆ **Legend:**
- **MAN**: Manufacturer
- **BC**: Barcode

◆ **Tube holder position:**
- **GBG214AS** Standard tube holder positions: Position 1, position 2, position 3, position 4
- **GBG215AS** Optional tube holder positions: Position 1, position 3, position 5, position 6

## 8.2. Tube holder position 1

Tab.1-2: Compatible tube position 1

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Becton D | Vacutainer | 368452 | K3-EDTA | 5ml | | MAN+BC | With cap | Rubber with groove |
| Becton D | Vacutainer | 367651 | K3-EDTA | 5ml | 2ml | MAN+BC | With cap | Hemogard |
| Becton D | Vacutainer | 367856 | K3-EDTA | 5ml | 3ml | MAN+BC | With cap | Hemogard |
| Becton D | Vacutainer | 367652 | K3-EDTA | 5ml | 3ml | MAN+BC | With cap | Hemogard |
| Becton D | Vacutainer | 367654 | K3-EDTA | 5ml | 4,5ml | MAN+BC | With cap | Hemogard |
| Terumo | Venoject II | VP-053SDK | K3-EDTA | 5ml | 3ml | MAN | With cap | UltraSeal |
| Terumo | Venoject | VT-050STK | K3-EDTA | 5ml | 5ml | MAN | With cap | Rubber with groove |
| Terumo | Venoject | VT-053STK | K3-EDTA | 5ml | 3ml | MAN | With cap | Rubber with groove |
| CML | ABX 3004002 | TH5C0C | K3-EDTA | 5ml | 4ml | MAN+BC | With cap | Rubber strongly not advisable |
| Greiner | Vacuette | 454087 | K3-EDTA | 5ml | 2ml | MAN+BC | With cap | Hemogard |
| Greiner | Vacuette | 454086 | K3-EDTA | 5ml | 3ml | MAN+BC | With cap | Hemogard |
| Greiner | Vacuette | 454036 | K3-EDTA | 5ml | 4ml | MAN+BC | With cap | Hemogard |
| Greiner | Vacuette | 454223 | K3-EDTA | 5ml | 4,5ml | MAN+BC | With cap | Hemogard |
| LDM Paris | | | EDTAKE | 5ml | 4,5ml | MAN+BC | With cap | Hemogard |

## 8.3. Tube holder position 2

Tab.1-3: Compatible tube position 2

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Becton D | Vacutainer | 6385 | K3-EDTA | 3ml | | MAN | *Without cap | Rubber strongly not advisable |
| Terumo | Venoject | VT-03STK | K3-EDTA | 3ml | 3ml | MAN | With cap | Rubber strongly not advisable |
| Greiner | Minicollect** | 450403 | K3-EDTA | 1ml | | | With cap | With valve |

*Because of the cap thickness and the lack of space between the holder and the top of the tube, the tube holder may not open correctly.

****Requires an additional adjustment procedure**: in the Menu «Service\Mechanical Systems\Sampling needle Adjustment», adjust the «Level» on «Position 2» to «8.0» instead of «3.0» (See Section 5: Maintenance & Troubleshooting, 2.3.4. Sampling needle adjustment)

## 8.4. Tube holder position 3

Tab.1-4: Compatible tube position 3

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Comar | R&D Systems | TX2B 18533IF | | 5ml | 2,2ml | | Without cap | With thread |

## 8.5. Tube holder position 4

Tab.1-5: Compatible tube position 4

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Sarstedt | | 901091 | | 0,5ml | | *Out of format | Without cap | Unlostable |
| KABE | ABX 3001001 | 0777008RED | | 0,5ml | | *Out of format | With cap | Unlostable |

*The tube accepts a small sticker (not supplied by the manufacturer).

## 8.6. Tube holder position 5

Tab.1-6: Compatible tube position 5

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Becton D | Microtainer | 365975 | | 0,5ml | | *Out of format | Without cap | **Microgard |

*The tube accepts a small sticker (not supplied by the manufacturer).
**Cap fitted with an adaptor (require another probe adjustment).

### 8.7. Tube holder position 6

Tab.1-7: Compatible tube position 6

| Manufact | Model | Part number | Additive | Vol | Vacuum | Stickers | Pirecing condition | Type of cap |
|---|---|---|---|---|---|---|---|---|
| Becton D | Microtainer | 365973 | | 0,5ml | | *Out of format | Without cap | |

*The tube accepts a small sticker (not supplied by the manufacturer).

## 9. Reagent specifications

**The HORIBA ABX reagents specified for this instrument have been approved in accordance with the European Directive 98/79/CE (Annex III) for in-vitro medical devices.**

- The CD ROM RAX055 delivered with your instrument provided Reagents, Controls and Calibrators leaflets/msds. Latest versions of these documents are available on www.horiba-abx.com/documentation.

## 10. Known interfering substances

### 10.1. White Blood Cells (Leukocytes)

**Chemotherapy** - Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocyte membranes which may cause low WBC counts. In these particular cases, CBC mode must not be used as WBC balance alarm (See Section 3: Specimen run & Results, 7.4.7. WBC balance) is disabled. It is recommended to run these samples in DIFF mode.

### 10.2. Plt (Platelets)

**Interference in the Platelet** result may occur for samples from Patients undergoing parenteral treatment with injection of lipid emulsion.

### 10.3. BAS# (Basophil cell count absolute), BAS% (Basophil percentage)

- **Over evaluation in the Basophil count:**
  Excessive number of leukocytes (leukocytosis) can cause artificial rise in the number of counted basophils due to the shifting of the leukocytes population in the zone of the basophil ones.

  Monocytes and Blasts show large granules and may shift on the basophil counting area. This may interfere with an accurate count.

  An abnormally of leukocytes (leukopenia) may increase too the basophil results. The elements present in the zone of basophil are brought back on a small total quantity of leukocytes, which increases the statistical error and may cause variabilities in the percentage.

  The weakness of leukocyte cells shown in certain diseases (Chronic Lymphocytic Leukomia) or during anti-cancer treatment (chemotherapy) can be translated on the basophilic channel by under evaluation of the leukocytes because of their destruction and thus cause a statistical increase in the basophil ones.

◆ **Under evaluation in the Basophil count:**
During leukomia, basophils may lose their cytochemical characters and react abnormally with the reagent. The destruction of the basophil cytoplasms prevents their differentiation with the other leukocytes.

The basophils with very small sizes (following treatments) may interfere with leukocyte counts, as cell sizes cannot be distinguished.

The abnormal basophils (degranulation following allergies) may interfere with leukocyte counts, because cell sizes cannot be distinguished and because they may lose their characteristic intracytoplasmic material.

# 11. Hgb measurement

◆ **Lysebio**
Reagent for erythrocyte lysis and cyanide-free determination of hemoglobin.
By addition of agent of lysis, hemoglobin is released. All the heme iron is oxidized and stabilized. Oxidation resulting complexes are quantified by spectrophotometry at a wavelength of 550nm.

# 12. Calibration verification (control blood sampling)

**The calibration on HORIBA ABX instruments is an exceptional procedure, which must be carried out particularly in case of certain technical interventions (installation, maintenance, service intervention). The calibration should not be carried out to compensate a drift on a results due for example to a clogging of the instrument.**

Before carrying out a calibration, it is essential to make sure that the instrument is in perfect condition of operation, and to follow the steps below:

1- Carry out a Concentrated cleaning procedure (refer to Section 5: Maintenance & Troubleshooting).

2- Perform two blank cycles to check the cleanliness of the instrument (if the blank measurement is not correct, please contact your HORIBA ABX representative).

3- Check the repeatability of the instrument by running 6 times a normal human blood without taking account of the first result (if the repeatability is not correct, please contact your HORIBA ABX representative).

4- Calculate the CV obtained out on the other 5 results. The values of CV must be lower than: WBC: 2%, RBC: 2%, HGB: 1%, HCT: 1%, PLA: 5%.

5- Run a control blood and check that the values are within the acceptable limits. If not, run a new control blood.

If the instrument is clean (blank cycles in conformity with the values given in the manual), the repeatability is correct (acceptable CV values) and the values of control are not within the acceptable limits, then it is possible to carry out the calibration:

6- Run at least 4 times Calibrator without taking the values of the first result into account.

7- Calibrate the instrument on the average of the last 3 results according to indications of the manual. Take care to respect the minimum and maximum calibration coefficient values given in the manual. Run 3 times again Calibrator to check the values.

8- Confirm the calibration while passing a control blood, the values have to be returned within acceptable limits.

9- After about thirty analyses of the day, check that values of MCV, MCH and MCHC are in conformity with the usual values of the laboratory.

# 13. Running specimen

◆ **Recommendations on the analysis mode selection (CBC or DIFF)**

When selecting CBC analysis, there is no control mode on WBC erroneous countings that may be caused by specific treatments on patients (See Section 1: Specifications, 5.3. Known interfering substances) and WBC balance (See Section 3: Specimen run & Results, 7.4.7. WBC balance).

# 14. Flags on WBC/BASO histogram

**CBC and DIFF mode**

**In certain cases, the L1 flag will not be triggered off because of the poor sensitivity of this flag (large platelet aggregates and/or erythroblasts that are beyond the electronic treshold). This happens in CBC mode only. Two additional flags LL and LL1 are available in DIFF mode and provide more reliability in anomaly detection. This mode should be recommended.**

# 15. WBC balance

**CBC mode Limitations**

**The WBC balance flag will indicate an instrument defect or it can also highlight a known interference (See Section 1: Specifications, 5.3. Known interfering substances).**
**In the case of pathology whose treatments weaken the leukocytic membranes, the agent of lysis of WBC channel can damaged the cells and give a lower leukocytes counting.**
**The LMNE+ flag will then be triggered off and a suspicion will be integrated to the WBC results. We thus recommend not to disable WBC balance flag and to work in DIFF mode for all the samples which can present this possible interference. Selecting the CBC mode will disable this control mode. It is thus recommended to use this mode for patient not presenting this type of interference.**

HORIBA ABX
Diagnostics

# Instrument User Manual Update

## RAM200AEN

## ABX Pentra 60 C+
## Instrument default settings

**Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.**

Date: 10/10/06

FORM 0860 - rev 1

# Instrument default settings

Tab.1-1: Concerned sections of the manual

| Section | Page | Paragraph | Item change |
|---|---|---|---|
| Instrument Configuration | | Type parametering | Addition of Instrument Default parametering charts |

# 1. General information

Type parametering:
- The following values are the software default values for pathological limits & thresholds (See "2.Pathological limits and thresholds, page 2"), Alarm levels ("3.Alarms levels, page 5"), Matrix thresholds (See "4.Matrix thresholds, page 8"), classified by types (standard, man, woman, Child 1,2,3).

Other modifications:
- Default values for XB limits ( See "6.XB limits, page 11").
- Default values for Quality Control coefficients ("5.QC Variation Coefficients, page 11" ).

# 2. Pathological limits and thresholds

From the menu: Settings \ Type Parametering

Tab.1-2: STANDARD

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 3.00 | 4.00 | 10.00 | 13.00 |
| RBC | 3.50 | 3.80 | 6.50 | 6.50 |
| HGB | 9.50 | 11.5 | 17.0 | 18.0 |
| HCT | 34.0 | 37.0 | 54.0 | 54.0 |
| MCV | 70 | 80 | 100 | 110 |
| MCH | 25.0 | 27.0 | 32.0 | 34.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 100 | 150 | 500 | 550 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 1.70 | 2.00 | 7.50 | 8.0 |
| LYM | 1.00 | 1.00 | 4.00 | 5.00 |
| MON | 0.00 | 0.20 | 1.00 | 1.50 |
| EOS | 0.00 | 0.00 | 0.50 | 0.70 |
| BAS | 0.00 | 0.00 | 0.20 | 0.25 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.25 | 0.25 |
| GCI# | 0 | 0 | 0.30 | 0.30 |

Tab.1-3: MAN

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 3.00 | 4.00 | 10.00 | 13.00 |
| RBC | 3.50 | 4.50 | 6.50 | 6.50 |
| HGB | 11.0 | 13.0 | 17.0 | 18.0 |
| HCT | 37.0 | 40.0 | 54.0 | 54.0 |
| MCV | 70 | 80 | 100 | 110 |
| MCH | 25.0 | 27.0 | 32.0 | 34.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 100 | 150 | 500 | 550 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 1.70 | 2.00 | 7.50 | 8.0 |
| LYM | 1.00 | 1.00 | 4.00 | 5.00 |
| MON | 0.00 | 0.20 | 1.00 | 1.50 |
| EOS | 0.00 | 0.00 | 0.50 | 0.70 |
| BAS | 0.00 | 0.00 | 0.20 | 0.25 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.25 | 0.25 |
| GCI# | 0 | 0 | 0.30 | 0.30 |

Tab.1-4: WOMAN

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 3.00 | 4.00 | 10.00 | 13.00 |
| RBC | 3.50 | 3.80 | 5.80 | 6.00 |
| HGB | 9.50 | 11.5 | 16.0 | 17.0 |
| HCT | 34.0 | 37.0 | 47.0 | 50.0 |
| MCV | 70 | 80 | 100 | 110 |
| MCH | 25.0 | 27.0 | 32.0 | 34.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 100 | 150 | 500 | 550 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 1.70 | 2.00 | 7.50 | 8.0 |
| LYM | 1.00 | 1.00 | 4.00 | 5.00 |
| MON | 0.00 | 0.20 | 1.00 | 1.50 |
| EOS | 0.00 | 0.00 | 0.50 | 0.70 |
| BAS | 0.00 | 0.00 | 0.20 | 0.25 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.25 | 0.25 |
| GCI# | 0 | 0 | 0.30 | 0.30 |

Tab.1-5: CHILD 1 (1 day old to 1 month old)

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 10.0 | 10.0 | 26.0 | 30.0 |
| RBC | 4.00 | 4.00 | 6.00 | 6.00 |
| HGB | 13.5 | 13.5 | 19.5 | 19.5 |
| HCT | 44.0 | 44.0 | 64.0 | 64.0 |
| MCV | 98 | 100 | 112 | 114 |
| MCH | 30.0 | 30.0 | 38.0 | 38.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 150 | 200 | 400 | 450 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 6.00 | 6.00 | 26.0 | 26.0 |
| LYM | 2.00 | 2.00 | 11.0 | 11.0 |
| MON | 0.40 | 0.40 | 3.10 | 3.10 |
| EOS | 0.00 | 0.00 | 0.85 | 0.85 |
| BAS | 0.00 | 0.00 | 0.65 | 0.65 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.35 | 0.35 |
| GCI# | 0 | 0 | 0.35 | 0.35 |

Tab.1-6: CHILD 2 (1 month old to 2 year old)

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 10.0 | 10.0 | 26.0 | 30.0 |
| RBC | 4.00 | 4.00 | 6.00 | 6.00 |
| HGB | 13.5 | 13.5 | 19.5 | 19.5 |
| HCT | 44.0 | 44.0 | 64.0 | 64.0 |
| MCV | 98 | 100 | 112 | 114 |
| MCH | 30.0 | 30.0 | 38.0 | 38.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 150 | 200 | 400 | 450 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 6.00 | 6.00 | 26.0 | 26.0 |
| LYM | 2.00 | 2.00 | 11.0 | 11.0 |
| MON | 0.40 | 0.40 | 3.10 | 3.10 |
| EOS | 0.00 | 0.00 | 0.85 | 0.85 |
| BAS | 0.00 | 0.00 | 0.65 | 0.65 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.35 | 0.35 |
| GCI# | 0 | 0 | 0.35 | 0.35 |

Tab.1-7: CHILD 3 (2 years old to 14 years old)

| | Panic L | Normal l | Normal h | Panic H |
|---|---|---|---|---|
| WBC | 4.50 | 4.50 | 13.5 | 15.0 |
| RBC | 4.00 | 4.00 | 5.40 | 5.40 |
| HGB | 11.0 | 11.5 | 14.5 | 15.0 |
| HCT | 37.0 | 37.0 | 45.0 | 45.0 |
| MCV | 75 | 77 | 91 | 93 |
| MCH | 24.0 | 24.0 | 30.0 | 30.0 |
| MCHC | 32.0 | 32.0 | 36.0 | 36.0 |
| RDW | 10.0 | 11.0 | 16.0 | 17.0 |
| PLT | 150 | 200 | 400 | 450 |
| MPV | 6 | 6 | 11 | 12 |
| PCT | 0.00 | 0.15 | 0.50 | 1.00 |
| PDW | 7 | 11 | 18 | 20 |
| NEU% | 0 | 0 | 99.9 | 99.9 |
| LYM% | 0 | 0 | 99.9 | 99.9 |
| MON% | 0 | 0 | 99.9 | 99.9 |
| EOS% | 0 | 0 | 99.9 | 99.9 |
| BAS% | 0 | 0 | 99.9 | 99.9 |
| NEU | 1.80 | 1.80 | 8.00 | 8.00 |
| LYM | 1.50 | 1.50 | 6.50 | 6.50 |
| MON | 0.00 | 0.00 | 0.8 | 0.8 |
| EOS | 0.00 | 0.00 | 0.60 | 0.60 |
| BAS | 0.00 | 0.00 | 0.20 | 0.30 |
| LYA% | 0 | 0 | 2.5 | 2.5 |
| CGI% | 0 | 0 | 3.0 | 3.0 |
| LYA# | 0 | 0 | 0.25 | 0.25 |
| GCI# | 0 | 0 | 0.30 | 0.30 |

# 3. Alarms levels

From the menu: Settings \ Type parametering

Tab.1-8: STANDARD

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

Tab.1-9: MAN

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

Tab.1-10: WOMAN

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

Tab.1-11: CHILD 1 (1 day old to 1 month old)

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

Tab.1-12: CHILD 2 (1 month old to 2 year old)

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

Tab.1-13: CHILD 3 (2 years old to 14 years old)

| | Level % | Level # |
|---|---|---|
| NO | 100 | 80 |
| LL | 100 | 80 |
| LL1 | 5 | 55 |
| NL | 3 | 120 |
| MN | 15 | 120 |
| RM | 0.7 | 999 |
| LN | 2.5 | 999 |
| RN | 1.1 | 999 |
| NE | 1.1 | 30 |
| L1 | 3 | 200 |
| | | |
| LMNE Reject | 50 | |
| MIC | 5 | |
| MAC | 45 | |
| MACp | 11 | |
| HGB | 3 | 60 |

# 4. Matrix thresholds

From the menu: Setting\ Type Parametering

Tab.1-14: STANDARD

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

Tab.1-15: MAN

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

Tab.1-16: WOMAN

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

Tab.1-17: CHILD 1

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

Tab.1-18: CHILD 2

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

Tab.1-19: CHILD 3

| Matrix threshold | Channel | |
|---|---|---|
| | Proposed | Current |
| NOL | 24 | 22 |
| NON | 27 | 25 |
| LL | 31 | 30 |
| LN | 35 | 35 |
| NOE | 50 | 48 |
| LMN | 69 | 70 |
| AL | 69 | 68 |
| LMU | 73 | 78 |
| LMD | 100 | 90 |
| MN | 100 | 90 |
| RM | 118 | 118 |
| RN | 118 | 118 |
| NL | 29 | 29 |
| RMN | 51 | 51 |
| NE | 82 | 82 |
| FLN | 2 | 2 |
| FNE | 2 | 2 |
| FMN | 2 | 2 |
| BA1 | 35 | 35 |
| BA2 | 110 | 110 |
| BA3 | 240 | 240 |

# 5. QC Variation Coefficients

From the menu: Settings \ QC & Calibration

Tab.1-20: Variation coefficients

| | MAX CV |
|---|---|
| WBC | 5 |
| RBC | 5 |
| HGB | 3 |
| HCT | 5 |
| MCV | 3 |
| MCH | 3 |
| MCHC | 3 |
| RDW | 10 |
| PLT | 10 |
| MPV | 10 |
| NEU % | 10 |
| LYM % | 10 |
| MON % | 35 |
| EOS % | 15 |
| BAS % | 10 |
| NEU | 10 |
| LYM | 10 |
| MON | 35 |
| EOS | 15 |
| BAS | 10 |

# 6. XB limits

From the menu: QC & Calibration\XB

Tab.1-21: XB Target value

| | Value | Tolerance |
|---|---|---|
| WBC | 7 | 3 |
| RBC | 5 | 1 |
| HGB | 14 | 3 |
| HCT | 45 | 5 |
| PLT | 320 | 100 |
| MCV | 90 | 10 |
| MCH | 29 | 2 |
| MCHC | 34 | 2 |
| RDW | 14 | 2 |

# Customer Addendum

## RAM146AEN

## Pentra 60C+

User manual Pentra 60C+
Update for Instrument version V2.3.0

Date: 16/11/05

FORM 0220 - rev 3

# User manual Pentra 60C+

Please, take note of the modifications on next pages. Please, cross out the appropriate sections in the user manual prior to inserting this addendum at the beginning of the user manual.

## Update for Instrument version V2.3.0

| Section | Page | Paragraph | Item change |
|---|---|---|---|
| 1. Specifications | 11-14 | 3.3 New linearity limits | Modification of the linearity limits |
| 3. Specimen run and results | 2 | 1.3 Pentra 60C+ startup | Warning on instrument left on standby more than 36 hours added at the end of the paragraph. |
| | 25 | 7.4.2. Flags giving an analysis default | Hgb < 0.7g/dL forced to 0 becomes:<br>Hgb ≤ 0.1g/dL forced to 0 |
| | 47 | 8.2 End of the day rinsing | Warning on instrument left on standby more than 36 hours added at the end of the paragraph. |

Table 1: Concerned sections Pentra 60C+

### 1. New linearity limits*

- Linearity range: The Manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.
- Linearity limits: Maximum and minimum values within instrument returns no dilution alarm.
- Visible range: Range values given by the instrument. These values (above linearity limits) are given as an indication. They are given associated with a «D» flag. This Visible range is outside Manufacturer's range.
- Linearity kits: Linearity was tested using available «Low Range» and «Full Range» Linearity Test kits. The Test kits were analyzed and data was computed according to the Manufacturer's instructions.
- Human Blood: Linearity was also obtained on human blood, using a minimum of 5 dilution points. The results of this study are as followed:

Table 2: Linearities

| Parameter | Linearity range | Linearity limits | Visible range | Error limit |
|---|---|---|---|---|
| WBC ($10^3$/µl) | 0.40 to 130.80 | 0 to 120 | 120 to 150 | ±0.3 ±7.5% |
| RBC ($10^6$/µl) | 0.23 to 9.76 | 0 to 8 | 8 to 18 | ±0.07 ±3% |
| HGB (g/dl) | 0 to 31.06 | 0 to 24 | 24 to 30 | ±0.3 ±3% |
| HCT (%) | 1.80 to 88.90 | 0 to 67 | 67 to 80 | ±2 ±3% |
| PLT ($10^3$/µl)<br>(for Hgb≥2g/dL) | 3.30 to 2007 | 0 to 1900 | 1900 to 2800 | ±10 ±12.5% |
| PLT ($10^3$/µl)<br>(for Hgb<2g/dL & Plt>15x$10^3$/$mm^3$) | 7 to 2895 | 0 to 2800 | 2800 to 3200 | ±10 ±12.5% |

* Source: 510K submission K030144

## 2. Flags giving an analysis default

Table 3: Results displayed

| Parameter | Linearity limits | Visible range | > Visible range |
|---|---|---|---|
| WBC | «result» | «result» + «D» | DIL |
| RBC | «result» | «result» + «D» | DIL |
| HGB | «result» | «result» + «D» | DIL |
| HCT | «result» | «result» + «D» | DIL |
| PLT (for Hgb≥2g/dL) | «result» | «result» + «D» | DIL |
| PLT (for Hgb<2g/dL & Plt>15x10$^3$/mm$^3$) | «result» | «result» + «D» | DIL |

Table 4: Results transmitted or printout

| Parameter | Linearity limits | Visible range | > Visible range |
|---|---|---|---|
| WBC | «result» | «result» + «D» | --.-- + D |
| RBC | «result» | «result» + «D» | --.-- + D |
| HGB | «result» | «result» + «D» | --.-- + D |
| HCT | «result» | «result» + «D» | --.-- + D |
| PLT (for Hgb≥2g/dL) | «result» | «result» + «D» | --.-- + D |
| PLT (for Hgb<2g/dL & Plt>15x10$^3$/mm$^3$) | «result» | «result» + «D» | --.-- + D |

Results displayed and printed out:
«PLT Concentrate» message indicates the triggering of the PLT extended linearity mode for an Hgb<2g/dL & Plt>15x10$^3$/mm$^3$ between 1900x10$^3$/µl and 2800x10$^3$/µl.

Results transmitted:
«C» message indicates the triggering of the PLT extended linearity mode for an Hgb<2g/dL & Plt>15x10$^3$/mm$^3$ between 1900x10$^3$/µl and 2800x10$^3$/µl.

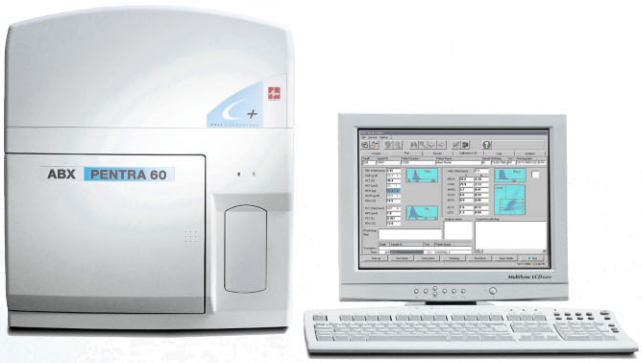
## 3. Possible start up problems for Pentra 60C+ systems

The following warning is added section 3 “Specimen run & results” at the end of the paragraph 1.3 “Pentra 60C+ startup”and at the end of the paragraph 8.2 “End of the day rinsing”:

It is mandatory to power down the system if not used for more than a 36 hour period. This eliminates the possibility of the Dilution Chambers evaporating and causing startup problems.

# Pentra 60 C+

## User Manual




P/n: RAB092D

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IVD

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# REVISIONS

| INDEX | TECHNICAL NOTE | SOFTWARE REVISION | SECTION | DATE |
|---|---|---|---|---|
| A | RAH774AA | V1.50 | ALL | 23/06/2000 |
| B | RAH792AA | V1.61 | ALL | 20/02/2001 |
| C | RAH873AA | V2.2 | ALL | 14/01/2002 |
| D | RAH986AA | V2.2.9 | ALL | 24/09/2003 |

- This document applies to the latest higher software version.
- When a subsequent software version changes the information in this document, a new issue will be released.

# 1. WARNINGS AND PRECAUTIONS

**NOTE**

NOTE: Emphasizes the important information especially helpful to the operator before, during or after a specific operational function.

**IMPORTANT**

IMPORTANT: Emphasizes an operating procedure that must be followed to avoid erroneous results.

**CAUTION**

CAUTION: Emphasizes an operating procedure that must be followed to avoid possible damage to the instrument or erroneous test results.

**WARNING**

WARNING: Flags a procedure that if not followed properly, can prove to be extremely hazardous to either the operator or the environment or both.

## 1.1. Warnings

• User manual must be enterely read and personnel trained by *ABX DIAGNOSTICS* before attempting to operate instrument. The user always operates with full knowledge and appreciation of instrument warnings, alarms and flags.
Always refer to labeling and *ABX DIAGNOSTICS* instructions in order to avoid to compromise system integrity.

• The *ABX PENTRA 60 C+* responds to the Standards and directives named in the Declaration of Conformity added at the beginning of this manual.

• The reagents and accessoiries stipulated by *ABX DIAGNOSTICS* have been validated in accordance with the European Directive for in-vitro medical devices (98/79/CE).

• The use of any other reagents and accessoiries may place at risk the performance of the instrument, engaging the Users reponsability. In this case, *ABX DIAGNOSTICS* takes no responsability for the device nor for the results rendered.

• Disposal gloves, eyes protection and lab coat must be worn by the operator. Local or national regulations must be applied in all the operations.

• Portable/mobile should not be used in proximity.

• All peripheral devices should be IEC compatible.

## 1.2. Limited garantee

• The duration of guarantee is stipulated in the Sales conditions associated with the purchase of this instrument. To validate the guarantee, ensure the following is adhered to:

1 - The system is operated under the instructions of this manual.

2 - Only software or hardware specified by *ABX DIAGNOSTICS* is installed on the instrument. This software must be the original copyrighted version.

3 - Services and repairs are provided by an *ABX DIAGNOSTICS* authorized technician, using only *ABX DIAGNOSTICS* approved spare parts.

4 - The electrical supply of the laboratory follows the national regulations.

5 - Specimens are collected and stored in normal conditions.

6 - Reagents used are those specified in this user manual.

7 - Proper tools are used when maintenance or troubleshooting operations are performed.

**CAUTION**

***If this instrument has been supplied to you by anyone other than ABX Diagnostics or an authorised representative, ABX Diagnostics cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorised representative.***

## 1.3. Safety precautions, electronic and moving parts

• The following parts must not be handled or checked by the user:
- Electrical power supply,
- Electronic components.

• Operator injury may occur from an electric shock. Electronic components can shock and injure the user. Do not tamper with the instrument and do not remove any components (covers, doors, panels and so on) unless otherwise instructed within this document.

• Danger ! The battery may explode if it is not replaced correctly ! Replace only with the same or equivalent type recommanded by the manufacturer. Dispose of used batteries according to the manufacturer's instructions.

• Moving parts:
It is strictly forbidden to disable sensors as it may cause operator injuries. Protection covers must not be opened during instrument operations.

## 1.4. Biological risks

• Consider all Specimens, Reagents, Calibrators, Controls, etc… that contain human blood or serum as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, Gloves, Lab coats, Safety glasses and/or Face shields, and follow other bio-safety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent bio-safety procedures.

• *ABX DIAGNOSTICS* uses disinfectant product for instrument decontamination and highly recommends it to decontaminate your instrument.

## 1.5. Instrument cleaning

***Instrument external cleaning***

• The external surfaces of the instrument must be decontaminated considering the biological environment.

WARNING

***Never spill liquid on the instrument.***

***Never use Disinfectant product* that contains alcohol.***

• Computer screen**:** Use a soft clot, slightly wet with disinfectant product*****. Wipe gently the screen and dry to remove any trace of moisture.

• All contaminated surfaces (covers, counting assembly area...): Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces.

• Stainless steel parts: Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces. Dry with a soft cloth.

*Products having the following microbiological properties:
• Bactericidal
• Fungicidal
• Active on Aspergillus fumigatus
• Active on Mycobacterium tuberculosis (B.K)
• Antiviral (VIH, HBV and rotavirus)

Product Example validated by ABX DIAGNOSTICS:
ANIOS detergent disinfectant ; *WIP'ANIOS ; ref: 1316.424*

NOTE

***Please also refer to the W.H.O (World Health Organization) guidelines: «Laboratory Biosafety Manual, 2nd edition», for further information.***

***Instrument internal cleaning***

• Concentrated cleaning: Counting chambers and hydraulics parts are decontaminated by using the «Concentrated cleaning» function as described in **2.1.2. Concentrated cleaning**, page 5-11.

***Sampling probe***

• Sampling probe must be decontaminated as follows:

1- Prepare a solution of Sodium Hypochlorite to 100ml/l.

2- Fill a 5ml tube with this solution.

3- Run 5 analysis on bleach.

NOTE

***Please also refer to the W.H.O (World Health Organization) guidelines: «Laboratory Biosafety Manual, 2nd edition», for further information.***

## 1.6. Graphics and symbols

| | | | |
|---|---|---|---|
| O | Switch off position | I | Switch on position |
| ~ | Alternating current | | Manufacturer |
| IVD | In Vitro Diagnostics medical device | CE | This product conforms to the EEC Standards and Directives named in the declaration of conformity |
| | Caution, consult accompanying documents | | Biological risk |
| REAGENT | Reagent | | Up |
| | Fragile, handle with care | | Keep dry |
| | Do not stack | | Temperature limitation |
| LOT | Batch code | REF | Catalogue number |
| | Use by | | Consult Instructions for use |
| CAL | Calibrator | CONTROL | Control |
| CONT | Content | | |

# 2. WORKING CONDITIONS

## 2.1. Environment

• The operation of the *ABX PENTRA 60 C+* should be restricted to indoor location use only ! Operation of the instrument at altitudes of over 3000 Meters (9800 feet) is not recommended. The instrument is designed for safety from voltages surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2(IEC EN 61010-1).
Please contact your local *ABX DIAGNOSTICS* representative for information regarding operation locations, when it does not comply with the recommended specifications.

## 2.2. Location

• The *ABX PENTRA 60 C+* should be placed on a clean and levelled table or workbench. Please note that the *ABX PENTRA 60 C+*, printer and reagents weigh approximately 40 kilograms (88 lbs).
Avoid exposure to sunlight.
Place your instrument where it is not exposed to water or vapor.
Place your instrument where it is free from vibration or shock.
Place your instrument where an independent power receptacle can be used.
Use a receptacle different from the one used by a device that easily generate noise such as a centrifuge, etc...

• Provide a space of at least 20 cm (8 inches) at the back of the instrument for arranging the power cable and tubings.

• The Power switch and Input voltage supply connection should always be accessible ! When positioning the system for operational use, leave the required amount of space for easy accessibility to these items.

## 2.3. Grounding

• Proper grounding is required when installing the system. Check the wall outlet ground (Earth) for proper grounding to the facilities electrical ground. If you are unsure of the outlet grounding, contact your facilities engineer to verify the proper outlet ground !

## 2.4. Humidity and temperature conditions

• *ABX PENTRA 60 C+* must operate between temperatures of 16 to 34°C (61 to 93°F). Maximum relative humidity should be 80% for temperatures up to 31°C (88°F) and decreasing linearly to 50% relative humidity at 40°C (104°F). If the system is kept at a temperature of 10°C (50°F) or less, it must be allowed to sit at room temperature for 1 hour before it can be used for operation.

## 2.5. Electromagnetic environment check

• The *ABX PENTRA 60 C+* has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.
In case of suspected electromagnetic noise, check that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, i. e. (Radar, X-rays, Scanners, Cell phones, etc...).

## 2.6. Environment protection

• Disposal Used accessories and consumables must be collected by a laboratory specialized in elimination and recycling of this kind of material according to the local legislation.

• Disposal *ABX PENTRA 60 C+* instrument:
It should be disposed of, in accordance with local legislation, and should be treated as being contaminated with blood. The appropriate biological precautions should be taken.

If any doubt, please contact your *ABX DIAGNOSTICS* representative service department.

## 2.7. Transport and storage conditions

• Storage temperature: -20°C +50°C

***Prior to the shipping of an instrument by transporter, whatever the destination, an external decontamination of the instrument must be carried out.***

## 2.8. Installation

• The *ABX PENTRA 60 C+* has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.
In case of suspected electromagnetic noise, check that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, i. e. (Radar, X-rays, Scanners, Cell phones, etc...).

• An *ABX DIAGNOSTICS* representative will install your instrument, computer, software and printer.

## 2.9. Package content

- Verify that all of the parts from the package list are present:

| ABX PENTRA 60 C+ | |
|---|---|
| 1x RAXXXX | User manual |
| 1x XBA453A | Barcode reader |
| 1x XAA504A | Lexmark e210 printer |
| 1x UC000002NUA2 | Workstation |
| 1x CCC006A | 15” Screen |
| 1x CBK045A (or CBK043A) | Keyboard Azerty (or Qwerty) |
| 1x P60CP001 | Pentra 60 C+ |
| 1x DACXXXX | Supply cable 220V or 110V |

# 3. PENTRA 60 C+ SOFTWARE

***Menu bar***

• Across the top of the window is the Menu bar, Menu bar displays the 4 available menus: **FILE**, **SERVICE**, **SETTING**, **?** (help).

• You can access the menus by clicking directly on the mouse or using the keyboard: Press ALT + the first letter of the menu name. For example: ALT + F open FILE menu.
Use UP and DOWN keys to select menu option or hit the underscored character in the option name.

***Tool bar***

• Below the Menu bar is the Tool bar, Tool bar displays common options:

Opens Print menu of selected tab

Sends selected area

New entry

Delete

Displays search screen

Switch from grid to page menu

Move to Prior file

Move to Next file

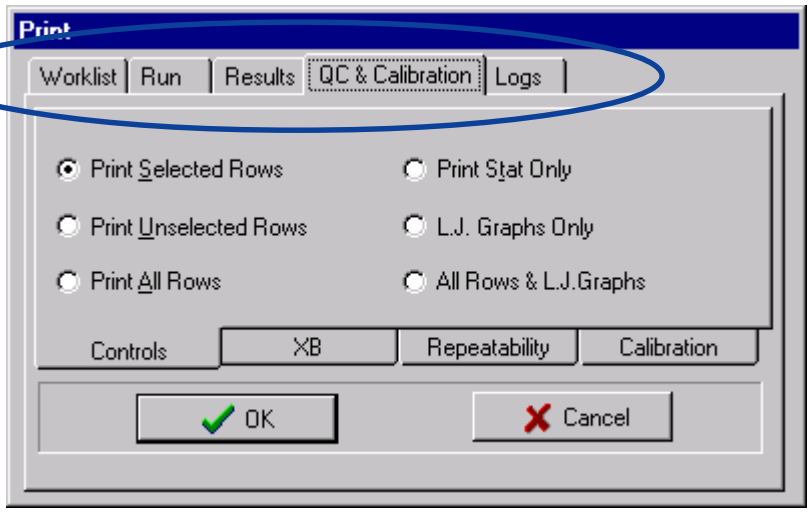
Validates result

Result rerun

Access to help

### *Tabs*

• Tabs are used to group functions, the main tabs are: **WORKLIST**, **RUN**, **RESULTS**, **CALIBRATION & QC**, **ANALYZER**. Click on the tab to enter or hit CTRL + TAB to move to the next one.




### *Buttons*

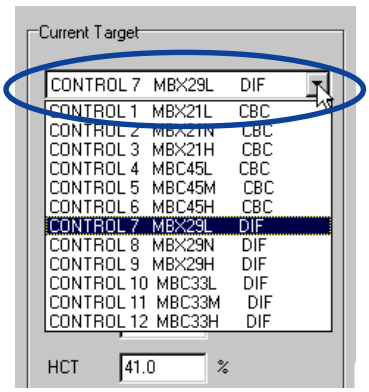
• A button like

, executes an action. If a button has a bold perimeter it can be activated by hitting ENTER key. When a button is rounded by a dotted line,

, it can be activated by hitting SPACE or ENTER key. TAB key allows movements from one button to the next one.

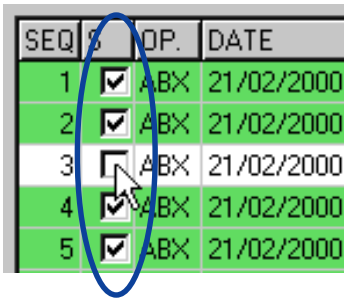
### *Scrolling list*

• A scrolling list is a little menu including a list of options and sometimes a field free to edit.



***Checked box***

• A checked box activates ☑ or desactivates ☐ an option:




***Radio button***

• A radio button allows the user to choose between options excluding each other:

***Fields***

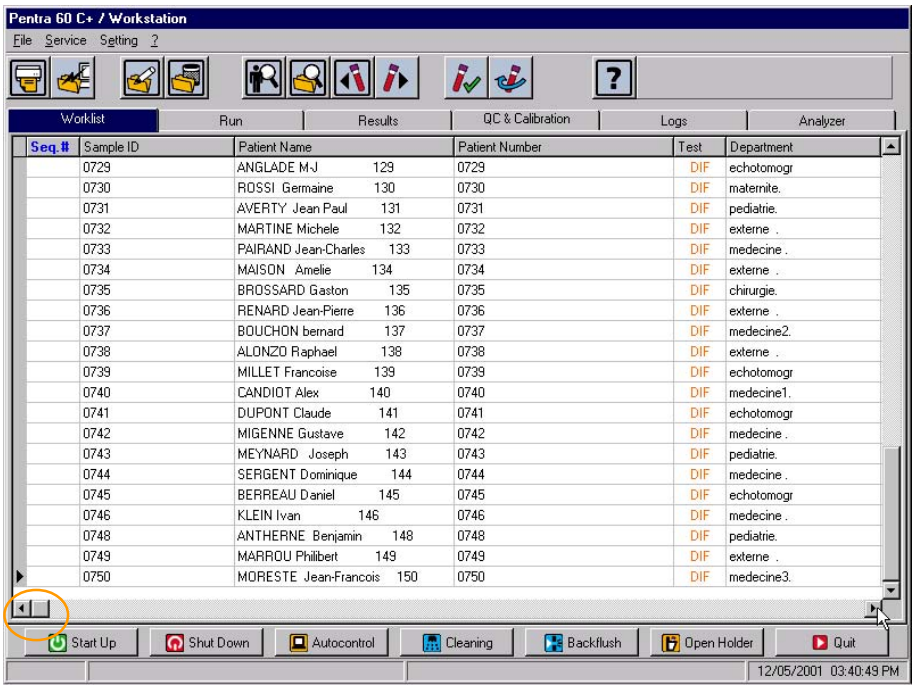
• A field is a rectangle area used to input or display data such as Name, Date, ...
Some fields have predefined format: Date, Number, Text, ...
For example: TEST field in WORKLIST is the analysis mode (CBC or DIF) for the concerned specimen, click, or move into TEST field and press ENTER, to swap between CBC and DIF mode.

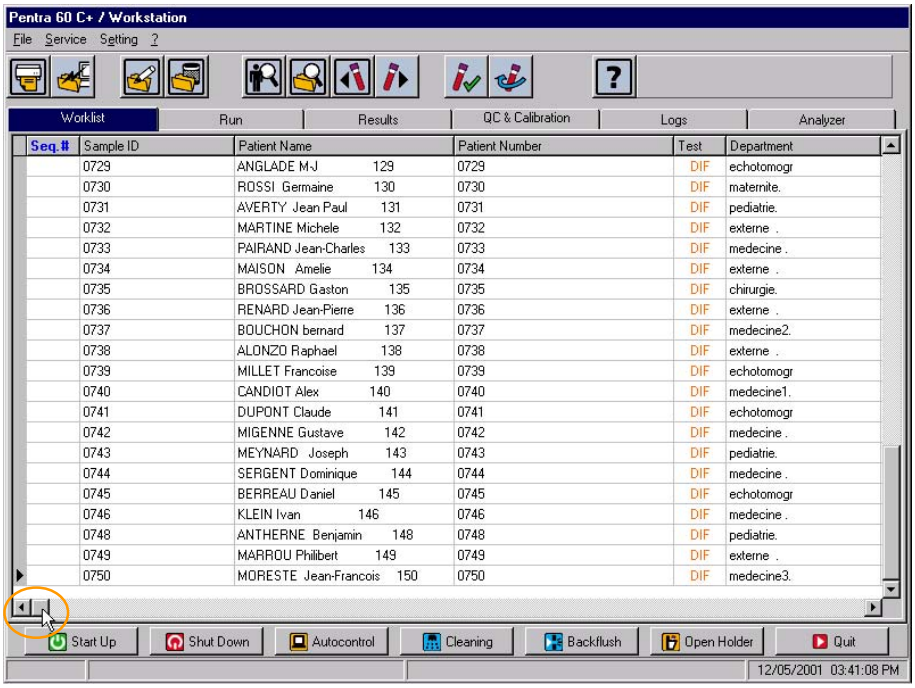
***Lists***

• Some information or fields are presented in a list format, use the mouse or direction keys to navigate inside the list, press ENTER to activate or change options.

***Sliders***

• When a window is too long or too high a vertical or horizontal slider appears. Use sliders to move from one part of the window to another. You can either drag the slider or click the arrows:


Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Seq.# Sample ID Patient Name Patient Number Test Department
0729 ANGLADE M-J 129 0729 DIF echotomogr
0730 ROSSI Germaine 130 0730 DIF maternite.
0731 AVERTY Jean Paul 131 0731 DIF pediatrie.
0732 MARTINE Michele 132 0732 DIF externe .
0733 PAIRAND Jean-Charles 133 0733 DIF medecine .
0734 MAISON Amelie 134 0734 DIF externe .
0735 BROSSARD Gaston 135 0735 DIF chirurgie.
0736 RENARD Jean-Pierre 136 0736 DIF externe .
0737 BOUCHON bernard 137 0737 DIF medecine2.
0738 ALONZO Raphael 138 0738 DIF externe .
0739 MILLET Francoise 139 0739 DIF echotomogr
0740 CANDIOT Alex 140 0740 DIF medecine1.
0741 DUPONT Claude 141 0741 DIF echotomogr
0742 MIGENNE Gustave 142 0742 DIF medecine .
0743 MEYNARD Joseph 143 0743 DIF pediatrie.
0744 SERGENT Dominique 144 0744 DIF medecine .
0745 BERREAU Daniel 145 0745 DIF echotomogr
0746 KLEIN Ivan 146 0746 DIF medecine .
0748 ANTHERNE Benjamin 148 0748 DIF pediatrie.
0749 MARROU Philibert 149 0749 DIF externe .
0750 MORESTE Jean-Francois 150 0750 DIF medecine3.
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
12/05/2001 03:40:49 PM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0749 MARROU Philibert 149 0749 DIF externe .
0750 MORESTE Jean-Francois 150 0750 DIF medecine3.
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
12/05/2001 03:41:08 PM

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# 1. TECHNICAL SPECIFICATIONS

• The *ABX PENTRA 60 C+* is a fully automated hematology analyzer used for in vitro diagnostic testing of whole blood specimens. A control station (or workstation) is directly connected to the instrument.

• The *ABX PENTRA 60 C+* is able to operate either in **CBC** mode (**C**ell **B**lood **C**ount:12 parameters) or in **CBC + 5DIFF** mode (**5** population **Diff**erential count: 26 parameters).

## 1.1. Parameters

### 1.1.1. CBC Mode

| | |
|---|---|
| **WBC** | **White Blood Cell** |
| RBC | Red Blood Cell |
| **Hgb** | **Hemoglobin concentration** |
| Hct | Hematocrit |
| **MCV** | **Mean Corpuscular Volume** |
| MCH | Mean Corpuscular Hemoglobin |
| **MCHC** | **Mean Corpuscular Hemoglobin Concentration** |
| RDW | Red Distribution Width |
| **Plt** | **Platelets** |
| PDW * | Platelet Distribution Width |
| **MPV** | **Mean Platelet Volume** |
| Pct * | Plateletcrit |

**** PDW and PCT have not been established as indications for this product,in the United States. The use of PCT and PDW should be restricted to research and Investigational measurements only.***

### 1.1.2. CBC + 5DIFF Mode

| | |
|---|---|
| WBC | White Blood Cell |
| LYM | Lymphocytes % and # |
| MON | Monocytes % and # |
| NEU | Neutrophils % and # |
| EOS | Eosinophils % and # |
| BAS | Basophils % and # |
| LIC * | Large Immature Cell % and # |
| ALY * | Atypical Lymphocyte % and # |
| | |
| RBC | Red Blood Cell |
| Hgb | Hemoglobin concentration |
| Hct | Hematocrit |
| MCV | Mean Corpuscular Volume |
| MCH | Mean Corpuscular Hemoglobin |
| MCHC | Mean Corpuscular Hemoglobin Concentration |
| RDW | Red Distribution Width |
| | |
| Plt | Platelets |
| PDW * | Platelet Distribution Width |
| MPV | Mean Platelet Volume |
| Pct * | Plateletcrit |

**** PCT, PDW, ALY and LIC have not been established as indications for this product,in the United States. The use of PCT, PDW, ALY and LIC should be restricted to research and Investigational measurements only.***

## 1.1.3. Units

| UNITS | | | | | | | |
|---|---|---|---|---|---|---|---|
| | WBC | RBC | HGB | HCT | PLT | MCV | |
| **STD** | $10^3/mm^3$ | $10^6/mm^3$ | g/dl | % | $10^3/mm^3$ | $\mu m^3$ | |
| **SI** | $10^9/l$ | $10^{12}/l$ | g/l | l/l | $10^9/l$ | fl | |
| **mmol/l** | $10^9/l$ | $10^{12}/l$ | mmol/l | l/l | $10^9/l$ | fl | |
| **JAPAN** | $10^2/mm^3$ | $10^4/mm^3$ | g/dl | % | $10^4/mm^3$ | $\mu m^3$ | |
| | MCH | MCHC | RDW | MPV | PCT | PDW | |
| **STD** | pg | g/dl | % | $\mu m^3$ | % | % | |
| **SI** | pg | g/l | % | fl | $10^{-2}/l$ | % | |
| **mmol/l** | fmol | mmol/l | % | fl | $10^{-2}/l$ | % | |
| **JAPAN** | pg | g/dl | % | $\mu m^3$ | % | % | |
| | LYC | LYC | MON | MON | NEU | NEU | EOS |
| **STD** | % | # | % | # | % | # | % |
| **SI** | % | # | % | # | % | # | % |
| **mmol/l** | % | # | % | # | % | # | % |
| **JAPAN** | % | # | % | # | % | # | % |
| | EOS | BAS | BAS | ALY | ALY | LIC | LIC |
| **STD** | # | % | # | % | # | % | # |
| **SI** | # | % | # | % | # | % | # |
| **mmol/l** | # | % | # | % | # | % | # |
| **JAPAN** | # | % | # | % | # | % | # |

- To select the set of units refers to Chapter 4. Instrument configuration

## 1.2. Throughput Analyses

- CBC Mode (CBC): ..... 60/h
- CBC + 5DIFF Mode (DIF): .. 60/h

## 1.3. Tube Identification

- By means of the ***ABX WORKSTATION***: Barcode labels or keyboard.

## 1.4. Reagents

- ***ABX DILUENT*** (20 litres)
- ***ABX CLEANER*** (1 litre, Integrated),
- ***ABX EOSINOFIX*** (1litre, Integrated),
- ***ABX BASOLYSE II*** (1 litre, Integrated),
- ***ABX ALPHALYSE*** or ***BIOLYSE*** (0.4 litre, Integrated)

## 1.5. Workstation Computer

- Processor frequency: ..... * Pentium II 350 Mhz (min.)
- Memory capacity: ..... * 128 Mb (min.)
- Hard drive: ..... * 4 Gb (min.)
- Floppy + CD-ROM
- Keyboard: ..... * 105 keys (Qwerty default or Option)
- Mouse: ..... * Standard PS/2 compatible
- RS232 port: ..... * x2 (Analyser/Local network)
- Screen: ..... * 15” monitor (800x600 min.)
- Operating System: ..... * Microsoft Windows NT 4.0 Service pack 4 GB or US

## 1.6. Measurements and computation

- Impedance for WBC, Plt, RBC, BASO.
- Photometry for Hgb.
- Impedance and light scattering for LYM, MON, NEU, EOS, ALY and LIC.
- Computation from stored data that was directly measured for Hct, MCV, MCH, MCHC, RDW, MPV, Pct, PDW.

# 2. PHYSICAL SPECIFICATIONS

## 2.1. Power requirements

- Power supplies: ..... * from 100Vac to 240Vac (±10%)
  ..... * 50 Hz to 60 Hz

- Power Consumption: ..... * Analyzer and computer: 400 VA
  ..... * Printer (Depends on printer see Printer's manual)
  ..... * EPSON EPL5900: 900 VA

## 2.2. Operating temperature and humidity

- 16 - 34°C (61 - 93°F) room temperature

- Maximum relative humidity 80% for temperatures up to 31°C (88°F) decreasing linearly to 50% relative humidity at 40°C (104°F).

## 2.3. Dimensions and Weight

- Analyzer dimensions: ..... * Height: approximately 516 mm (20.3 in.)
  ..... * Width: approximately 444 mm (17.5 in.)
  ..... * Depth: approximately 481 mm (19 in.)
- Analyzer weight: ..... * approximately 35Kgs (77lbs)

- Computer dimensions: ..... * See computer's manual
- Computer weight: ..... * See computer's manual

## 2.4. Minimum specimen volume

- CBC Mode (CBC): ..... * 30µl
- CBC + 5DIFF Mode (DIF): .. * 53µl

## 2.5. Dilution ratios

- WBC/BASO ..... * 1/200
- LMNE ..... * 1/80
- RBC/Plt ..... * 1/10 000
- Hgb ..... * 1/250

## 2.6. Hgb measurement

- Hgb chamber, LED 555 nm.
- Modified Drabkin method (cyanmethemoglobin)

- Light source ..... * Electroluminescent diode
- Wavelength ..... * 550nm ± 10nm

## 2.7. Counting aperture diameters

- WBC/BASO ..... * 80 µm
- LMNE ..... * 60 µm
- RBC/Plt ..... * 50 µm

## 2.8. Reagent consumption (ml)

| Cycle | Reagent | | | | | Approximate Duration |
|---|---|---|---|---|---|---|
| | Diluent | Basolyse II | Cleaner | Eosinofix | Alphalyse | |
| CBC (CBC) | 22.6 | 2.1 | 0.9 | X | 0.4 | 60” |
| 5DIFF (DIF) | 28.5 | 2.1 | 0.9 | 1 | 0.4 | 60” |
| Startup* | 65.4 | 2.1 | 3.7 | 1 | 1.4 | 4’50” |
| Shutdown | 27 | X | 14 | X | 1 | 3’00” |
| Diluent Prime | 44.9 | X | X | X | X | 3’10” |
| Cleaner Prime | X | X | 24.8 | X | X | 1’20” |
| Eosinofix Prime | X | X | X | 23.6 | X | 1’10” |
| Basolyse II Prime | X | 23.6 | 1.1 | X | X | 2’20” |
| Lyse Prime | 2.1 | X | X | X | 8.4 | 1’30” |
| All Reagents Prime | 49 | 24 | 25.1 | 24 | 8.2 | 6’ |
| Autoclean | 13.4 | 1 | 1 | 1 | 0.3 | 1’35” |
| Autocontrol | 25.4 | X | 1.4 | X | 1 | 1’50” |

**** for one background count only (maxi = 3)***

# 3. SUMMARY OF PERFORMANCE DATA

## 3.1. Precision (Reproducibility)*

• The *ABX PENTRA 60 C+* was initially calibrated with Minocal Calibrator (Lot No. CX322, Expiry Date: 05-Aug-2002).

• Three levels of ABX MINOTROL material (Lot No: JX108) were run in duplicate once daily for a prolonged period (26th July 2002 to 30 August 2002) on all parameters.
The results were used to quantify within run precision, and Total Precision in accordance with the NCCLS EP 5-A Guidelines.

| Parameter | ABX Minotrol Control | Within run SD | SD of run means | SD of daily means | Total Precision (SD) |
|---|---|---|---|---|---|
| WBC | JX108 Low | 0.001 | N/A | N/A | 0.001 |
| | JX108 Normal | 0.008 | N/A | N/A | 0.013 |
| | JX108 High | 0.031 | N/A | N/A | 0.045 |
| RBC | JX108 Low | 0.000 | N/A | N/A | 0.000 |
| | JX108 Normal | 0.001 | N/A | N/A | 0.001 |
| | JX108 High | 0.002 | N/A | N/A | 0.003 |
| HGB | JX108 Low | 0.001 | N/A | N/A | 0.001 |
| | JX108 Normal | 0.002 | N/A | N/A | 0.007 |
| | JX108 High | 0.005 | N/A | N/A | 0.012 |
| HCT | JX108 Low | 0.021 | N/A | N/A | 0.025 |
| | JX108 Normal | 0.064 | N/A | N/A | 0.122 |
| | JX108 High | 0.104 | N/A | N/A | 0.181 |
| PLT | JX108 Low | 6.271 | N/A | N/A | 20.646 |
| | JX108 Normal | 40.229 | N/A | N/A | 72.103 |
| | JX108 High | 154.146 | N/A | N/A | 381.388 |
| **Parameter** | **ABX Minotrol Control** | **Within run CV%** | **CV% of run means** | **CV% of daily means** | **Total Precision (CV%)** |
| WBC | JX108 Low | 1.8 | N/A | N/A | 1.93 |
| | JX108 Normal | 0.9 | N/A | N/A | 1.12 |
| | JX108 High | 0.9 | N/A | N/A | 1.05 |
| RBC | JX108 Low | 0.8 | N/A | N/A | 0.86 |
| | JX108 Normal | 0.6 | N/A | N/A | 0.79 |
| | JX108 High | 0.7 | N/A | N/A | 0.88 |
| HGB | JX108 Low | 0.4 | N/A | N/A | 0.57 |
| | JX108 Normal | 0.3 | N/A | N/A | 0.59 |
| | JX108 High | 0.4 | N/A | N/A | 0.60 |
| HCT | JX108 Low | 0.9 | N/A | N/A | 0.99 |
| | JX108 Normal | 0.7 | N/A | N/A | 0.97 |
| | JX108 High | 0.7 | N/A | N/A | 0.89 |
| PLT | JX108 Low | 3.1 | N/A | N/A | 5.69 |
| | JX108 Normal | 2.6 | N/A | N/A | 3.46 |
| | JX108 High | 2.5 | N/A | N/A | 4.01 |

*Source: 510K submission K030144

Precision claims*

| Parameter | % CV | Nominal Values |
|---|---|---|
| WBC | < 2.0% | 10.0 x $10^3$/$mm^3$ |
| RBC | < 2.0% | 4.67 x $10^6$/$mm^3$ |
| HGB | < 1.0% | 13.6 g/dl |
| HCT | < 2.0% | 36.0 % |
| PLT | < 5.0% | 243 x $10^3$/$mm^3$ |

*Source: 510K submission K030144

## 3.2. Precision (Repeatability)

- Based on 10 consecutive samples of the same fresh whole blood sample without alarm:

| Parameters | %CV | Test level |
|---|---|---|
| WBC | <2% | at 10x$10^3$/$mm^3$ |
| RBC | <2% | at 5x$10^6$/$mm^3$ |
| Plt | <5% | at 300x$10^3$/$mm^3$ |
| Hgb | <1% | at 15 g/dL |
| Hct | <2% | at 45% |

## 3.3. Linearity*

• **Linearity range:** The Manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.

• **Linearity kits**
Linearity was tested using available «Low Range» and «Full Range» Linearity Test kits. The Test kits were analyzed and data was computed according to the Manufacturer's instructions.

• **Human Blood**
Linearity was also obtained on human blood, using a minimum of 5 dilution points. The re-sults of this study are as followed:

| Parameters | Linearity Range | Difference (Which ever is greater) |
|---|---|---|
| WBC | 0 to 120x10$^3$/mm$^3$ | +/-0.2 or +/-3% |
| RBC | 0 to 10x10$^6$/mm$^3$ | +/-0.05 or +/-2% |
| Plt | 0 to 2200x10$^3$/mm$^3$ | +/-10 or +/-6% |
| Hgb | 0.7 to 30 g/dL | +/-0.3 or +/-2% |
| Hct | 0.7 to 80% | +/-2 or +/-3% |

*Not validated for the U.S.A. Market.

## 3.4. Carryover

• The *ABX PENTRA 60 C+* carry-over effects were evaluated by assaying a sample with high cell concentrations three consecutive times (i1-3), followed immediately by testing a diluted sample consecutively 3 times (j1-3).

$$\text{Carryover} = \frac{(j1\text{-}j3)}{(i3\text{-}j3)} \times 100$$

Carry-over % is then:

| | WBC | RBC | HGB | PLT |
|---|---|---|---|---|
| Mean low levels | 1.06 | 1.58 | 5.28 | 31.33 |
| Mean high levels | 58.81 | 6.37 | 22.03 | 1106.67 |
| Carry over % | -0.260 | 0.000 | -0.179 | -0.186 |

This is the method as described in *Guidelines for the Evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications*. ISLH, *14 January, 1994.*

• Carry-over Conclusion:
Results provided are extremely satisfactory. In order to provide for eventual possibilities within the laboratory environment the following claims shall be made :

| | WBC | RBC | HGB | PLT |
|---|---|---|---|---|
| Claims | < 2.0% | < 2.0% | < 2.0% | < 2.0% |

*Source: 510K submission K030144

## 3.5. Normal ranges*

| Parameters | Male | Female |
|---|---|---|
| WBC ($10^3$/µL) | 4 - 10 | 4 - 10 |
| RBC ($10^6$/µL) | 4.50 - 6.50 | 3.80 - 5.80 |
| HGB (g/dL) | 13.0 - 17.0 | 11.5 - 16.0 |
| HCT (%) | 40.0 - 54.0 | 37.0 - 47.0 |
| MCV (µm$^3$) | 80 - 100 | 80 - 100 |
| MCH (pg) | 27.0 - 32.0 | 27.0 - 32.0 |
| MCHC (g/dL) | 32.0 - 36.0 | 32.0 - 36.0 |
| RDW (%) | 11.0 - 16.0 | 11.0 - 16.0 |
| PLT ($10^3$/µL) | 150 - 500 | 150 - 500 |
| MPV (µm$^3$) | 6 - 11 | 6 - 11 |
| PCT (%) | 0.15 - 0.50 | 0.15 - 0.50 |
| PDW (%) | 11 - 18 | 11 - 18 |
| NEU (%) | 50 - 80 | 50 - 80 |
| LYM (%) | 25 - 50 | 25 - 50 |
| MON (%) | 2 - 10 | 2 - 10 |
| EOS (%) | 0 - 5 | 0 - 5 |
| BAS (%) | 0 - 2 | 0 - 2 |

IMPORTANT

***Expected values will vary with sample population and/or geographical location. It is highly recommended that each Laboratory establish its own Normal ranges based upon the local population!***

*Bibliography:
AIDE MEMOIRE D'HEMATOLOGIE
Prof : C.SULTAN / M. GOUAULT- HELMANN / M. IMBERT
Service Central d'Hématologie de l'Hopital Henri Mondor
Faculté de médecine de Créteil (Paris XII)

## 3.6. Accuracy*

• The data shows good correlation between results achieved on the *ABX PENTRA 60 C+* versus the reference system, which can be resumed as follows:

| Parameter | $R^2$ (Comparison of means) | Accuracy Claims |
|---|---|---|
| WBC | 0.997 | >0.95 |
| PLT | 0.998 | >0.95 |
| RBC | N/A | N/A |
| HGB | N/A | N/A |
| HCT | N/A | N/A |
| LYM | N/A | N/A |
| NEU | N/A | N/A |
| MON | N/A | N/A |
| EOS | N/A | N/A |
| BAS | N/A | N/A |

*Source: 510K submission K030144

## 3.7. Leukocyte differential count

• Not available at the time of publication.

## 3.8. Sample stability study

• Not available at the time of publication.

## 3.9. Flags giving an analysis default

***Results exceeding instrument capacities***

| Parameter | Displayed | Printed out | Transmitted |
|---|---|---|---|
| 0<WBC<120 (x10³/mm³) | «result» | «result» | «result» |
| WBC>120 | ---- + D | ---- + D | --.-- + D |
| 0<RBC<10 (x10⁶/mm³) | «result» | «result» | «result» |
| 10<RBC<18 | «result»+«D» | «result»+«D» | «result»+«D» |
| 0<PLT<2200 (x10³/mm³) | «result» | «result» | «result» |
| PLT>2200 | ---- + D | ---- + D | --.-- + D |
| 0.7<HGB<30 (g/dL) | «result» | «result» | «result» |
| HGB>30 | ---- + D | ---- + D | --.-- + D |
| 0.7<HCT<80 (%) | «result» | «result» | «result» |
| HCT>80 | ---- + D | ---- + D | --.-- + D |

NOTE

***Use the instrument diluent to dilute the sample if a «D» flag occurs on WBC or Hct.***

# 4. REAGENTS SPECIFICATIONS

## 4.1. Reagent specifications

• In order for the instrument to operate correctly, high-quality reagents must be used. *ABX DIAGNOSTICS* provides all the necessary reagents.

**NOTE**

***The ABX Diagnostics reagents specified for this instrument may have followed one or both of the approval methods below:***
***1 - have been registered by the A.F.S.S.A.P.S. «Agence Française de Sécurité Sanitaire des Produits de Santé» according to the procedure relative to laboratory reagents used for biological analyses.***
***2 - or approved in accordance with the European Directive 98/79/CE (Annex III) for in-vitro medical devices.***
***Please refer to the packaging of each reagent concerned to establish the approval method.***

• Refer to **Chapter** Annex of this manual for all reagent speifications.

## 4.2. Waste handling precautions

**WARNING**

***When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc...). Follow your local and /or national guidelines for biohazard waste disposal.***

• If required, waste can be neutralized before being discarded. Follow your laboratory's protocol when neutralizing and disposing of waste.

• Dispose of the waste container according to the local or national regulatory requirements.

# 5. LIMITATIONS

**WARNING**

***Whilst every effort is taken by ABX Diagnostics to investigate and indicate all known interference's, it is by no means possible to guarantee that all interference's have been identified. At all times, results should be validated and communicated only once all information relating to the patient has been assessed and taken into account.***

## 5.1. Maintenance

• In *Chapter 5. Maintenance & Troubleshooting*, specific maintenance procedures are listed. The maintenance procedures identified are mandatory for proper use and operation of the *ABX PENTRA 60 C+*. Failure to execute any of these recommended procedures may result in poor reliability of the system.

**IMPORTANT**

***Failure to execute any of these recommended procedures may result in poor reliability of the system.***

## 5.2. Blood specimens

• Verification of any abnormal test result (including flagged results or results outside of the normal range) should be performed using reference methods or other standard laboratory procedures for conclusive verification of the results. The sections below list known limitations of automated blood cell counters which use the principles of impedance and light absorbance as principles of measurement.

## 5.3. Known interfering substances

***White Blood Cells (Leukocytes):***

WBC results that exceed the linearity limits of the system will require dilution of the blood sample (Leukemia sample followed by a leukopenia).
Re-assaying the diluted sample will help to obtain the correct assay value.

**Unlysed Red Cells** - In some rare instances, the erythrocytes in the blood sample may not be completely lysed. These non-lysed red blood cells may be detected on the WBC histogram with an L1 alarm or as an elevated baseline on the side (leading edge) of the lymphocytes population. Non-lysed erythrocytes will cause a falsely elevated WBC count.

**Multiple myeloma** - The precipitation of proteins in multiple myeloma patients may give high WBC counts.

**Leukemia** - A very low WBC count may result from this disease because of possible increased fragility of the leukocytes leading to destruction of some of these cells during counting. These white cell fragments will also interfere with the white cell differential parameters.
These white cell fragments will also interfere with the white cell partial differential parameters: LYM% + #, MON% + #, GRAN% + #. A suspiciously low WBC count may also be seen in patients with lymphocytic leukemias due to the presence of abnormally small lymphocytes which may not be counted by the instrument.

**Chemotherapy** - Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocytes which may cause low WBC counts.

**Cryoglobulins** - Increased levels of cryoglobulin that may be associated with myeloma, carcinoma, leukemia, macroglobulinemia, lymphoproliferative disorders, metastic tumors, autoimmune disorders, infections, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc, which can increase the WBC, RBC or PLT counts and the HGB concentration. The specimen must be warmed up to 37°C (99°F) in a bain marie for 30 minutes and analyzed again immediately after (analyzer or manual method).

**Macrothrombocytes** - in excessive numbers may affect and increase Leukocyte numeration.

***RBC: Red Blood Cells (Erythrocytes)***

The red blood cell dilution contains all the formed elements in the blood: erythrocytes, leukocytes and platelets. During erythrocytes counting (red blood cells), platelets are not counted as their size falls below the minimum threshold.

**Agglutinated erythrocytes** - May cause a low incorrect RBC count. Blood samples containing the agglutinated red blood cells may be suspected by elevated MCH and MCHC values and shown by examination of the stained blood film.

**Cold agglutinins** - IgM immunoglobulins which are high in cold agglutinin disease may cause lower RBC and PLT counts and increase MCV.

***Hgb (Hemoglobin):***

**Turbidity of the blood sample** - Any number of physiological and/or therapeutic factors may produce high incorrect HGB results. To obtain accurate hemoglobin results when increased turbidity of the blood sample occurs, determine the cause of the turbidity and follow the appropriate method below:

**High WBC**: An extremely high WBC will cause excessive light scatter. In these cases use reference (manual) methods.The diluted sample should be centrifuged, and the supernatant fluid measured with a spectrophotometer.

**High lipid concentration**: A high concentration of lipids in the blood sample will give the plasma a "milky" appearance. This condition can occur with hyperlipidemia, hyperproteinemia (as in gammapathies) and hyperbilirubinemia. Accurate hemoglobin determinations can be achieved by using reference (manual) methods and a plasma blank.

**Increased turbidity** may also be seen in cases where the red blood cells are resistant to lysing. This condition will cause an incorrect high HGB result, but may be detected by observing the abnormal MCH, MCHC values, and the increased baseline on the leading edge of the WBC histogram. Erroneous hemoglobin results will cause the results of the MCH and MCHC to be incorrect as well.

**Fetal bloods** - The mixing of fetal and maternal bloods may produce a high inaccurate HGB value.

***Hct (Hematocrit)***

**Red blood cells agglutination** - May produce an inaccurate HCT and MCV values. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film In such cases, manual methods may be required to obtain an accurate HCT value.

***MCV (Mean Corpuscular Volume)***

**Red blood cell agglutination** - May produce an inaccurate MCV value. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film. In such cases, manual methods may be required to obtain an accurate MCV value.

**Excessive numbers of large platelets** and/or the presence of an excessively high WBC count may interfere with the accurate determination of the MCV value. In such cases, careful examination of the stained blood film may reveal the error.

***MCH (Mean Corpuscular Hemoglobin)***

The MCH is determined according to HGB value and the RBC count. The limitations listed for the HGB and RBC will have an effect on the MCH and may cause inaccurate values.

***MCHC (Mean Corpuscular Hemoglobin Concentration)***

The MCHC is determined according to the HGB and HCT values. The limitations listed for the HGB and HCT will have an effect on the MCHC and may cause inaccurate values.

***RDW (Red blood cell Distribution Width)***

The red blood cell distribution width is determined according to the RBC count.

**Nutritional deficiency or blood transfusion** - May cause high RDW results due to iron and/or cobalamin and /or folate deficiency.

***Plt (Platelets)***

**Very small erythrocytes** (microcytes), erythrocyte fragments (schizocytes) and WBC fragments may interfere with the proper counting of platelets and cause elevated PLT counts.

**Agglutinated erythrocytes** - May trap platelets, causing an erroneously low platelet count. The presence of agglutinated erythrocytes may be detected by observation of abnormal MCH and MCHC values and by careful examination of the stained blood film.

**Giant platelets in excessive numbers** - may cause a low inaccurate platelet count as these large platelets may exceed the upper threshold for the platelet parameter and are not counted.

**Chemotherapy** - Cytotoxic and immunosuppressive drugs may increase the fragility of these cells which may cause low PLT counts. Reference (manual) methods may be necessary to obtain an accurate platelet count.

**Hemolysis** - Hemolysed specimens contain red cell stroma which may increase platelet counts.

**A.C.D. blood** - Blood anticoagulated with acid-citrate-dextrose may contain clumped platelet which could decrease the platelet count.

**Elevated triglycerides and/or cholesterol**: may interfere with correct platelet counting.

**Platelet agglutination** - Clumped platelets may cause a decreased platelet count and/or a high WBC count. The specimen should be recollected in sodium citrate anticoagulant to ensure the anticoagulated character depending on agglutination and reanalyzed only for the platelet count. The final PLT result must be corrected for the sodium citrate dilution effect. However, these platelet clumps do trigger flags L1, LL and LL1.

***MPV (Mean Platelet Volume)***

**Giant platelets** that exceed the upper threshold of the Platelet parameter may not be counted as platelets. Consequently, these larger platelets will not be included in the instrument's calculation of Mean Platelet Volume.

**Very small erythrocytes** (microcytes), erythrocytic fragments (Schizocytes) and white blood cell fragments may interfere with the proper counting and sizing of Platelets.

**Agglutinated erythrocytes** - May trap Platelets, causing an incorrect MPV result. The presence of agglutinated erythrocytes may be detected by observation of abnormal MCH and MCHC values and by careful examination of the stained blood film.

**Chemotherapy** - May also affect the sizing of PLTs.

IMPORTANT

***Blood samples collected in EDTA will not maintain a stable Mean Platelet Volume. Platelets collected in EDTA swell depending on the time post-collection and storage temperature.***

***LYM# (Lymphocyte count absolute value), LYM% (Lymphocyte percentage)***

The Lymphocyte count is derived from the WBC count. The presence of erythroblasts, certain parasites and erythrocytes that are resistant to lysis may interfere with an accurate LYM count. Limitations listed for the WBC count pertain to the LYM # and % counts as well.

***MON# (mononuclear cell count absolute), MON% (Mononuclear percentage)***

The mononuclear cell count absolute is derived from the WBC count. The presence of large lymphocytes, atypical lymphocytes, blasts and an excessive number of basophils may interfere with an accurate monocyte count. Limitations listed for the WBC count pertain to the MON # and % counts as well.

***NEU# (neutrophil count absolute), NEU% (Neutrophil percentage)***

The neutrophils cell count is derived from the WBC cell count. The excessive presence of eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate neutrophils count.

***EOS# (Eosinophil cell count absolute), EOS% (Eosinophil percentage)***

The eosinophil cell count is derived from the WBC cell count. The presence of abnormal granules (degranulated areas, toxic granules...) may interfere with the eosinophil counting.

***BAS# (Basophil cell count absolute), BAS% (Basophil percentage)***

The Basophil cell count is derived from the WBC cell count.

Pentra 60 C+

# DESCRIPTION & TECHNOLOGY


1. PENTRA 60 C+ DESCRIPTION ..... 2-2
1.1. Pentra 60 C+ front side ..... 2-2
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HORIBA DIAGNOSTICS

# 1. PENTRA 60 C+ DESCRIPTION

## 1.1. Pentra 60 C+ front side

**+ Cover**

• *Before any attempt to remove the cover, open the pneumatic access door.*

**+ Pneumatic access door**

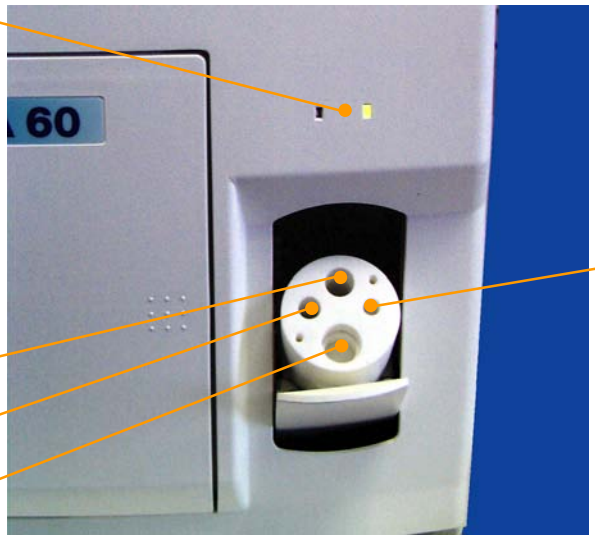
• *Allows the operator to access hydraulics parts for maintenance operations. It is mandatory to keep the door locked during the measuring cycles as it ensures the heating of the dilutions.*

**+ Reagent access door**

• *Access to the reagent bottles in order to replace them when empty.*

**+ Tube holder**

• *This door gives access to the sample tube holder. Cap piercing and sampling are initiated by the downward movement of the sampling needle.*




+ LEDs
- *When Green LED is lit instrument is ready to sample,*
- *When Green and Red LEDs are blinking alternatly, instrument is busy sampling,*
- *When Red LED is lit instrument is running.*

+ Sampling position 1
*For 5ml tubes*

+ Sampling position 2
*For 3ml tubes*

+ Sampling position 3
*For Controls / Calibrators & Latex*

+ Sampling position 4
*For microcontainer*

## 1.2. Pentra 60 C+ back side

+ Serial number label

+ «Printer»
*Connector for printer*

+ Main supply cable

+ «Diluent» input
*Cristal tube 3 x 6, length: 2 meters maximum*

+ «Waste» output
*Cristal tube 4 x 6, length: 2 meters maximum*

+ «Barcode»
*Connector for barcode reader (Unused)*

+ «RS 232 Output»
*Connector Workstation (Unused)*

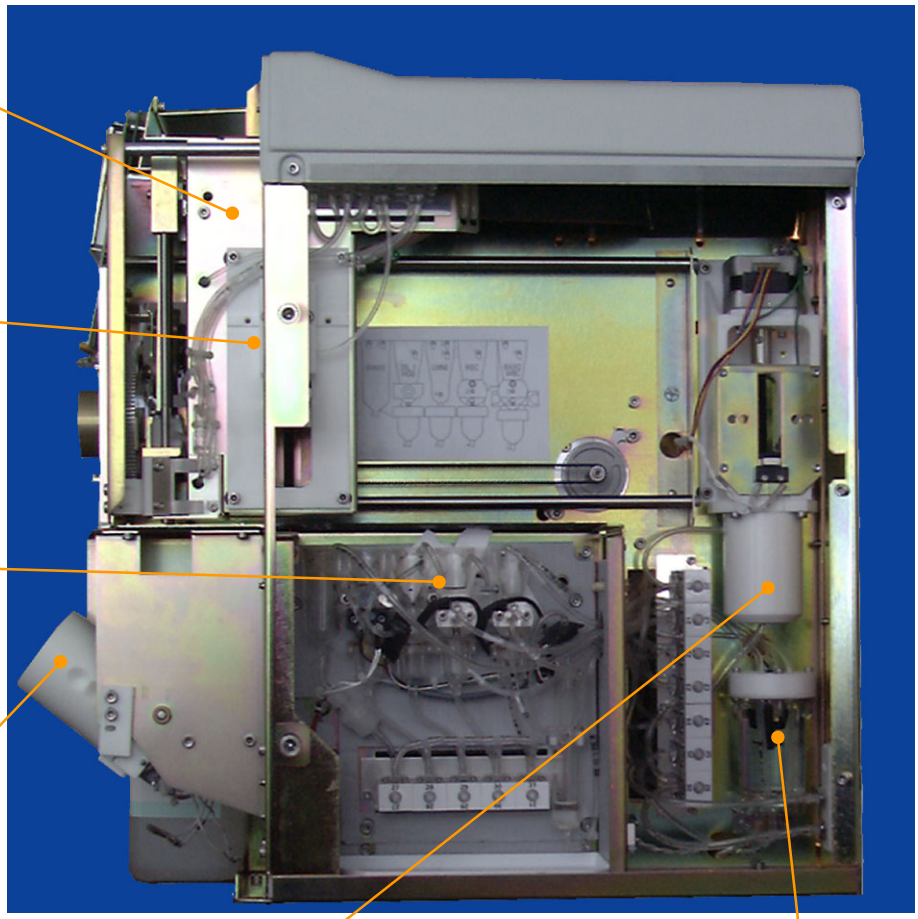
## 1.3. Mechanical and hydraulic modules

### + Piercing carriage
- *Ensures needle positioning for the different sampling stages and distribution,*
- *Supports the sampling syringe and the blood distribution.*

### + Sampling syringe
- *Distributes portions of the specimen into the dilution chambers,*
- *Takes the sample from the first dilution and distributes it into the RBC/PLT chamber.*

### + Count assembly
- *Receives the different rinsings and dilutions,*
- *Regulates the temperature of dilutions,*
- *Provides the dilutions for WBC/BASOS, RBC/Plt and Hgb.*

### + Tube holder
- *4 positions according to the sampling tube characteristics,*
- *Selected position is the hole facing the inside of the instrument*



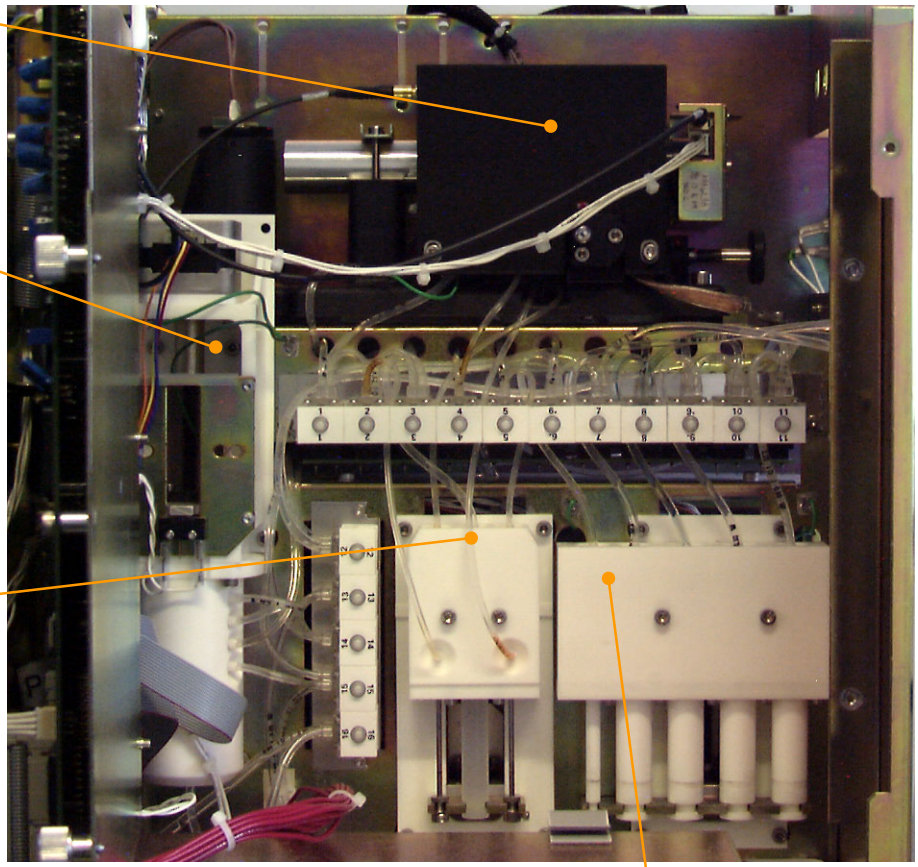
### + Draining syringe
- *Drains the chambers,*
- *Bubbles the mixtures,*
- *Transfers, by vacuum, the LMNE specimen from the mixing chamber towards to the injector of the optical flowcell.*

### + Diluent tank
- *Contains the necessary diluent for an analysis cycle,*
- *Prevents Diluent degassing as it is being aspirated by the syringes,*
- *Is vacuum filled by the counting syringe.*

+ Optical bench
• *Ensures the support and adjustment of the flowcell, lamp, and optical and electronic elements.*

+ Counting syringe
• *Ensures the vacuum for the WBC and BASOS counts,*
• *Ensures the vacuum for the RBC and the Plts counts,*
• *Ensures the vacuum for filling the diluent tank with diluent.*

+ LMNE Syringe assembly
• *Ensures the correct proportioning of the stop diluent in the LMNE chamber,*
• *Injects the specimen into the flowcell,*
• *Injects the interior and exterior sheath into the flowcell.*



+ Reagent Syringe assembly
• *Ensures the correct proportioning of the reagents:*
• *Lysing reagent for hemoglobin (ABX **ALPHALYSE**),*
• *Cleaning reagent (ABX **CLEANER**),*
• *Lysing reagent for DIFF count (ABX **EOSINOFIX**),*
• *Diluent used for the dilutions (ABX **DILUENT**) except the LMNE stop diluent,*
• *Lysing reagent for WBC/BASO (ABX **BASOLYSE II**).*

## + Main board

*Located on the left side of the instrument. The board is fastened onto a door in order to allow access to the fluidic modules.*

### Main functions of the board

- *Amplifies, processes and counts the following signals:*

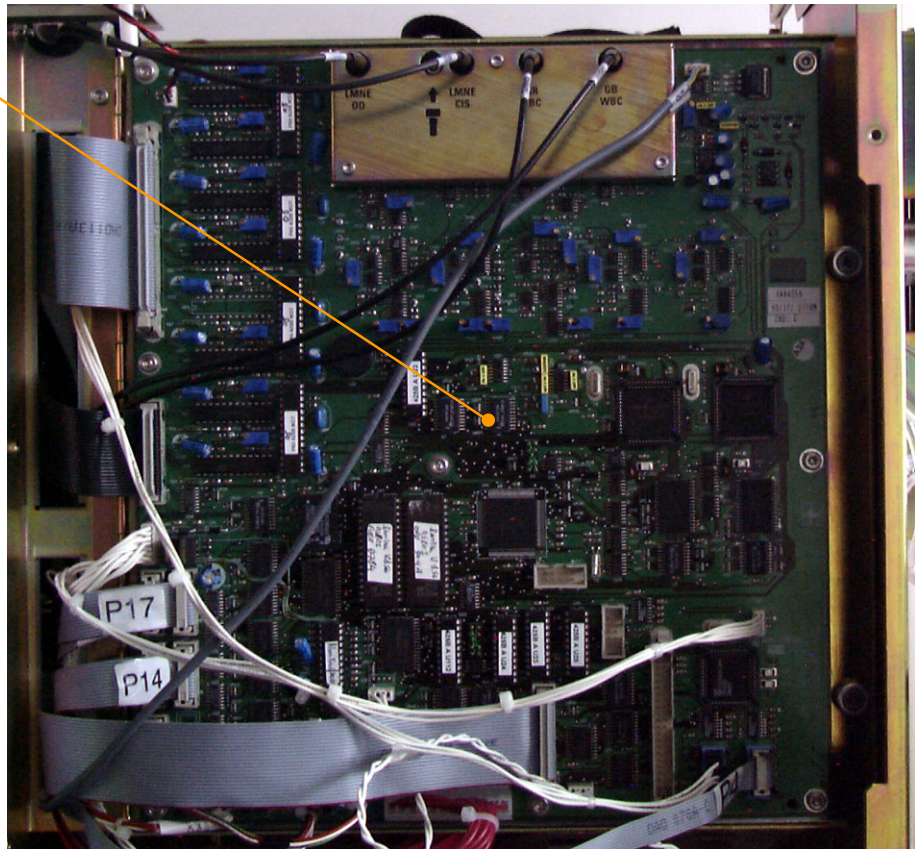
*- Resistive signals and LMNE optical signals,*

*- RBC Signal,*

*- Plt signal,*

*- WBC/BASO signals.*

- *Measures hemoglobin,*
- *Pilots the motorised elements.*




## CAUTION

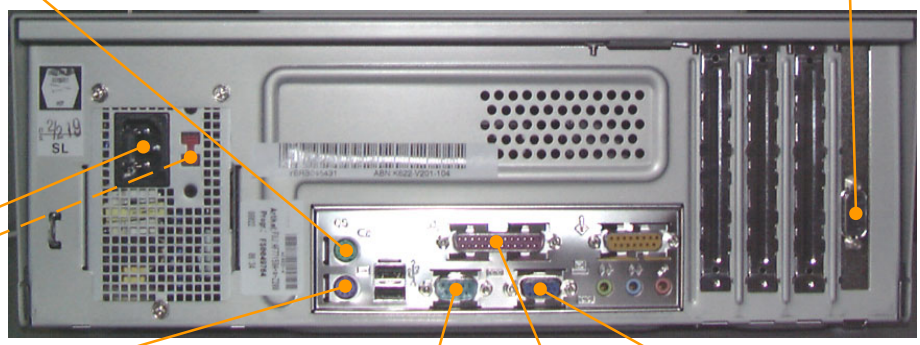
***When opening the main board support panel, be careful not to disconnect or damage electric cables.***

## 1.4. Computer's front side

NOTE

***Diagrams on this page are given for information, computers from one country to another may be different.***

## 1.5. Computer's back side

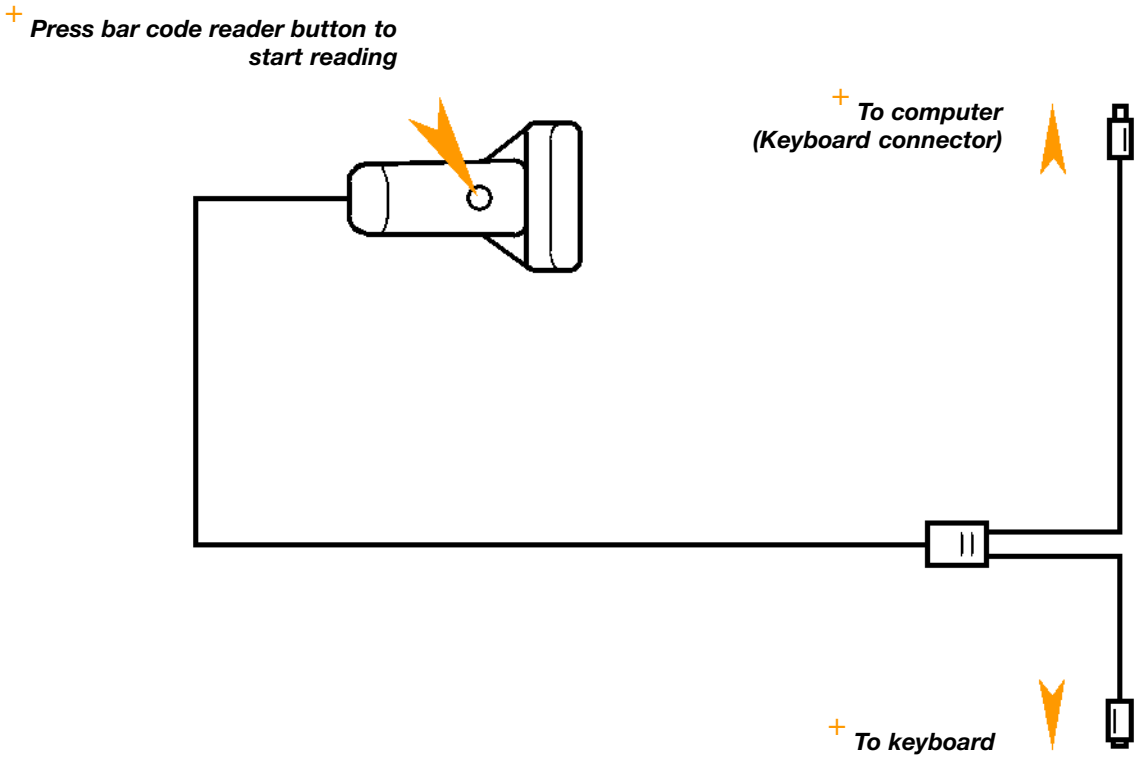

+ Mouse port
Connect standard mouse to this port.
+ Host connector
Connect to laboratory's network
+ Main supply
From 100Vac to 240Vac.
+ Keyboard connector
Supports standard 105 keys keyboards and barcode reader.
+ Analyzer connector
Connect to ABX PENTRA 60 C+.
+ Screen connector
SVGA output .
+ Printer connector

NOTE

***Other connectors on the back of the computer are described in the computer's manual.***

## 1.6. Barcode connection

- Connect barcode reader between computer and keyboard as shown below:



# 2. MEASURING PRINCIPLES

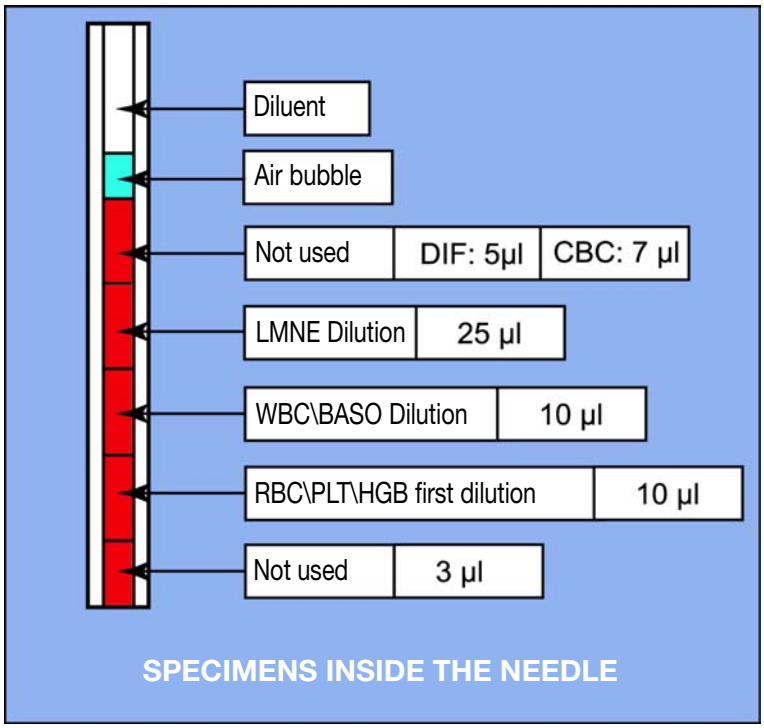
## 2.1. Multi Distribution Sampling System (MDSS)

+ ABX PENTRA 60 C+ *analysis cycle needs 3 blood specimens distributed as follows:*

- *one specimen for the first RBC/Plt dilution and the Hgb measurement.*
- *another specimen for the BASO/WBC count.*
- *the last specimen for the LMNE matrix.*

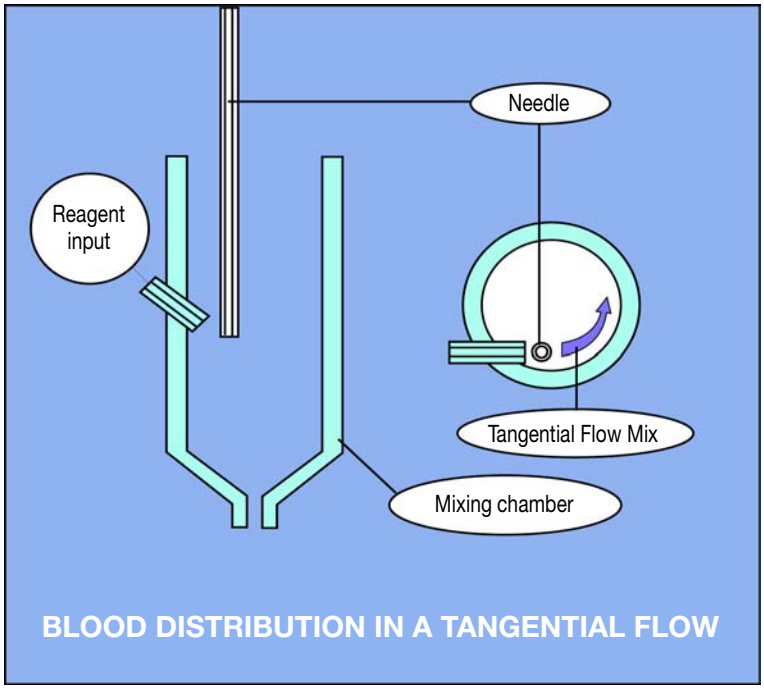
***These 3 specimens** are provided by means of a «multidistribution» principle:*

- *53 µl of blood are aspirated inside the needle (sufficient volume for all dilutions) then divided up and distributed to the chambers with reagents.*
- *Extremities of the specimen are not delivered to the dilutions.*




SPECIMENS INSIDE THE NEEDLE

+ ***Specimen* distribution** *in the chambers is carried out in a* tangential flow of reagent *which allows perfect mixing of the dilution and avoids any viscosity problems (this multi distribution in a reagent flow is an* ABX DIAGNOSTICS *patent).*




BLOOD DISTRIBUTION IN A TANGENTIAL FLOW

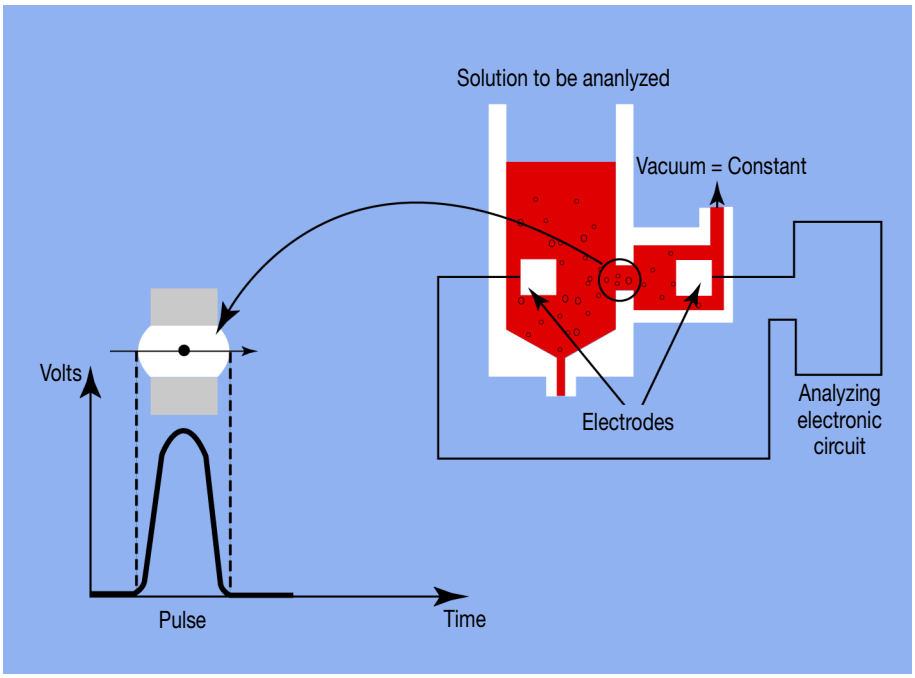
## 2.2. RBC / Plt detection principles

***Measurement of impedance variation generated by the passage of cells through a calibrated micro aperture.***

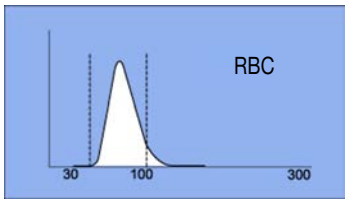
- *The specimen is diluted in an electrolytic diluent (current conductor) and pulled through the calibrated micro-aperture. Two electrodes are placed on either side of the aperture. Electric current passes through the electrodes continuously.*

- *When the cell passes through the aperture, electric resistance between the two electrodes increases proportionately with the cell volume.*

- *The generated impulses have a very low voltage, which the amplification circuit increases, so that the electronic system can analyze them and eliminate the background noise.*

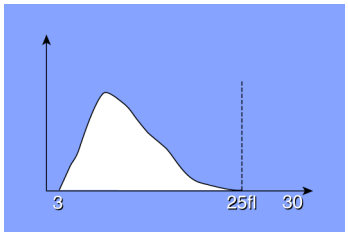



| TECHNICAL CHARACTERISTICS OF THE RED BLOOD CELL AND PLATELET COUNTS | | | |
|---|---|---|---|
| Initial blood volume | 10 µl | Method | Impedance |
| Vol. ABX DILUENT | 2500 µl | Aperture diameter | 50 µm |
| Final dilution rate** | 1/10000 | Count vacuum | 200 mb |
| Temperature of reaction | 35°C | Count period | 2 X 5 seconds |
| **: TWO SUCCESSIVE DILUTIONS ARE CARRIED OUT : PRIMARY DILUTION FOR RBC AND PLT: | | | |
| Blood (µl): 10 | | | |
| ABX DILUENT (µL): | 1700 | dilution: | 1/170 |
| SECONDARY DILUTION RBC AND PLT (FROM THE PRIMARY DILUTION): | | | |
| Dilution (µl): 42.5 | | | |
| ABX DILUENT(µL): | 2500 | dilution: | 1/58.8 |
| FINAL DILUTION: 1/170 X 1/58.8 =1/10000 | | | |




***Results***

• Number of cells counted per volume unit x Calibration coefficient.




***Histograms***

**RBC**: Distribution curves on 256 counting channels from 30fl to 300fl.

**Plt**: Distribution curves on 256 channels from 2fl to a mobile threshold. This threshold moves according to the microcyte population present in the analysis area.

## 2.3. Hgb measurement

• The hemoglobin released by the lysis of the red blood cells combines with the potassium cyanide to form the chromogenous cyanmethemoglobin compound. This compound is then measured through the optical part of the first dilution chamber using a spectrophotometric technique at a wavelength of 550 nm.

| TECHNICAL CHARACTERISTICS FOR THE MEASUREMENT OF THE HEMOGLOBIN: | | | |
|---|---|---|---|
| Volume of blood | 10 µl | Method | Photometry |
| Volume ABX DILUENT | 1700 µl | Wavelength | 550 nm |
| Volume ABX ALPHALYSE | 400 µl | | |
| Complement ABX DILUENT | 400 µl | | |
| Final dilution rate | 1/250 | | |
| Temperature of reaction | 35°C | | |

***Result***

• Final Hgb result represents: Absorbance value obtained x coefficient of calibration.

## 2.4. Hct measurement

• The height of the impulse generated by the passage of a cell through the micro-aperture is directly proportional to the volume of the analyzed RBC.

• The hematocrit is measured as a function of the numeric integration of the MCV.

## 2.5. RDW calculation

• The study of the RBC distribution detects erythrocyte anomalies linked to anisocytosis.
A Red Cell Distribution Width (RDW) will enable you to follow the evolution of the width of the curve in relation to the cell number and average volume.

$$RDW = \frac{K\ SD}{MCV}$$

With:
• K = system constant
• SD = Determined standard deviation according to statistical studies on cell distribution.
• MCV = Mean Corpuscular Volume of erythrocytes

## 2.6. MCV, MCH, MCHC calculation

• MCV (Mean Cell Volume) is calculated directly from the RBC histogram.

• MCH (Mean Cell Hemoglobin) is calculated from the Hgb value and the RBC number.
The mean hemoglobin weight in each RBC is given by the formula:

$$MCH\ (pg) = \frac{Hgb}{RBC} \times 10$$

• MCHC (Mean Corpuscular Hemoglobin Contained) is calculated according to the Hgb and Hct values. Mean Hgb concentration in the total volume of RBC is given by the formula:

$$MCHC\ (g/dL) = \frac{Hgb}{Hct} \times 100$$

## 2.7. MPV Measurement

• The MPV (Mean Platelet Volume) is directly derived from the analysis of the platelet distribution curve.

## 2.8. Pct calculation

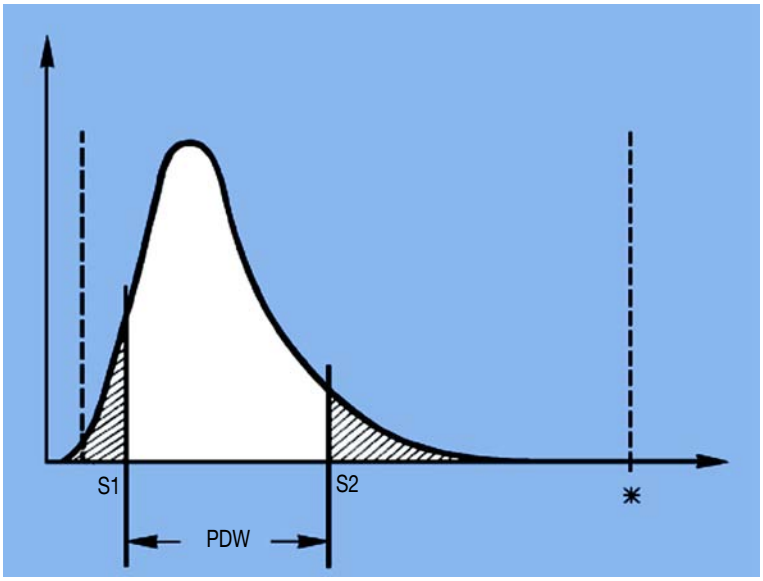
• Thrombocrit is calculated according to the formula:

$$Pct\% = \frac{Plt\ (10^3/\mu l) \times MPV\ (\mu m^3)}{10\ 000}$$

## 2.9. PDW calculation

• *PDW (Platelet Distribution Width) is calculated from the Plt histogram.*

• *The PDW is represented by the width of the curve between 15% of the number of platelets starting from 2 fl (S1), and 15% of the number of platelets beginning with the variable top threshold (S2).*



## 2.10. WBC and differential count

### 2.10.1. General principles

The WBC count is carried out twice by two different sensors:
- In the BASO count chamber at the same time as the BASOS count,
- In the optical chamber during the acquisition of the LMNE matrix.

The reference count is the one obtained in the WBC and BASO count chamber.

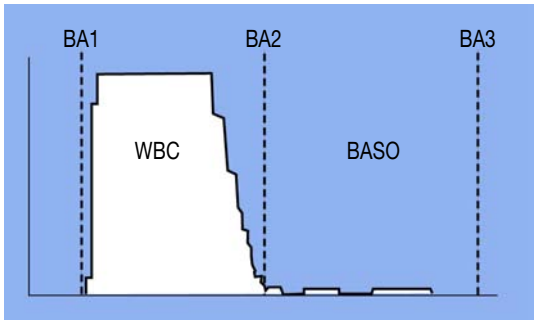
### 2.10.2. BASO / WBC Count

- Detection principle is the same as for RBC.

Differentiation betwen BASOs and other leukocytes is obtained by means of the **BASOLYSE II** specific lysing action.

- All the WBCs are counted between the electrical threshold <**0**> threshold <**BA3**>.

The basophils are located from threshold <**BA2**> to threshold <**BA3**>.




| Technical Characteristics of the WBC/BASO count | | | |
|---|---|---|---|
| Blood volume | 10 µl | Method | Impedance |
| BASOLYSE II volume | 2000 µl | Ruby diameter | 80 µm |
| Dilution rate | 1/200 | Depression of count | 200 mb |
| Reaction temperature | 35 ° C | Duration of the count | 2 X 6 seconds |

***Results***

**WBC**: Number of cells per volume x coefficient of calibration.

**BASO**: Number of cells per volume x coefficient of calibration in percentage regarding the total number of leukocytes (BASO + WBC nuclei)

## 2.10.3. LMNE matrix

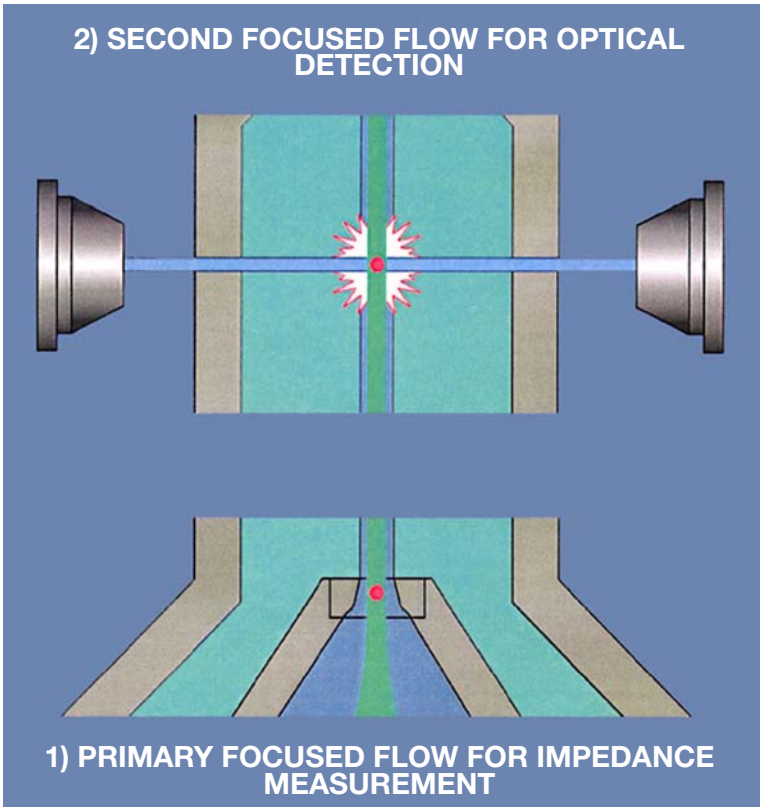
• *The WBC and Differential count are based on 3 essential principles:*

*1*- The double hydrodynamic sleeving *«DHSS» (ABX DIAGNOSTICS patent)*

*2*- The volume measurement *impedance changes.*

*3*- The measurement of transmitted light *with 0° angle, which permits a response according to the internal structure of each element and its absorbance by means of incident light diffusion.*

• *25µl of whole blood is delivered to the LMNE chamber in a flow of EOSINOFIX. This reagent lyses the RBC, stabilizes the WBC in their native forms and stains the eosinophil nuclei with a specific coloration.*
• *The solution is then stabilized with diluent and transferred to the measuring chamber. Each cell is measured both in absorbance (cytochemistry) and resistivity (volume).*

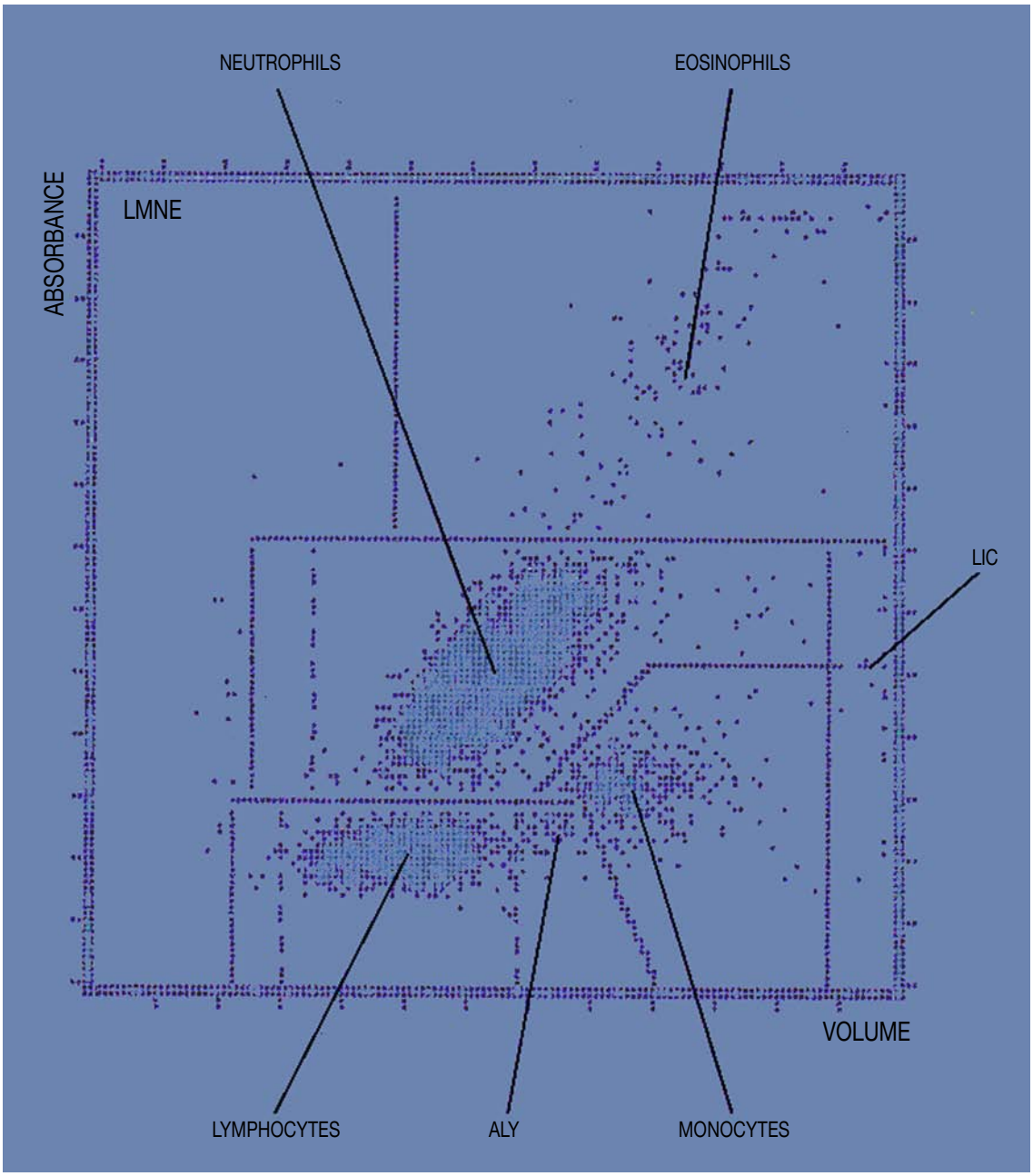



**TECHNICAL CHARACTERISTICS OF THE WBC COUNT DURING THE ACQUISITION OF THE MATRIX**

| | | | |
|---|---|---|---|
| Blood volume | 25 µl | Method | Impedance with hydrofocus |
| Eosinofix volume | 1000 µl | Ruby diameter | 60 µm |
| Diluent volume | 1000 µl | Flow diameter | 42 µm |
| Final dilution rate | 1/80 | Injection duration | 12 seconds |
| Reaction temperature | 35 ° C | Volume injected | 72 µl |
| Incubation duration | 12 s. | | |

***Results***

• From these measurements, a matrix is drawn up with volumes on the X-axis and optical transmission on the Y-axis.
The study of the matrix image permits the clear differentiation of 4 out of 5 leukocyte populations. As a matter of fact, the basophil population is very small compared to the other 5 in a small blood sample.


NEUTROPHILS
EOSINOPHILS
ABSORBANCE
LMNE
LIC
VOLUME
LYMPHOCYTES
ALY
MONOCYTES

***MONOCYTES**: The monocytes, being cells with large kidney shaped nuclei and a large non-granular cytoplasm, will neither be scattered nor absorb a large amount of light. They will therefore be positioned in the lower part of the optical axis but clearly to the right of the volume axis. Certain large monocytes can be found on the right side of the matrix in the lower LIC (Large Immature Cells) zone. The immature granulocytic cells are detected by their larger volumes and by the presence of granules which increase the intensity of the scattered light. Therefore, cells such as metamyelocytes will be found clearly to the right of the neutrophils and nearly at the same level. Myelocytes and promyelocytes will be found in saturation position on the far right of the matrix. These last three populations will be counted as LIC (Large Immature Cells) and their given results are included in the neutrophil value. The blast cells will be found generally to the right of the monocytes, and, as such, will increase the LIC count. Small blasts will be found between the normal lymphocytes and monocytes. Platelets and debris from erythrocyte lysis represent the background noise population located in the lower left area of the matrix. Most of the population partition thresholds are fixed and give the limits of the morphological normality of leukocytes. Changes in the morphology of a population will be expressed on the matrix by a shifting of the corresponding population.*

***LYMPHOCYTES**: The lymphocytes being small with regular shape, are positioned in the lower part of both the optical axis and volume axis. Normal lymphocyte populations are generally observed with a good volume homogeneity. Large lymphocytes are detected in the ALY (Atypical Lymphocytes) zone, where reactive lymphoid forms, stimulated lymphocytes and plasmocytes are also to be found. The far left side of the lymphocyte zone should normally be empty, but when small lymphocytes are present, population may exist in this area. The presence of platelet aggregates is detected by a distribution pattern that moves from the origin of the matrix (background zone) into the lymphocyte zone. The NRBCs with their cytoplasmic membranes lysed like the erythrocytes, will have their nuclei situated to the far left side of the lymphocyte zone.*

***EOSINOPHILS**: With reagent action on cytoplasmic membranes, the leukocytes keep their native size and only eosinophils are colored for optical separation. Eosinophils will be situated in the upper part of the optical Y-axis due to their strong absorbance qualities and their size, which is nearly equivalent to large neutrophils.*

***NEUTROPHILS**: The neutrophils, with their cytoplasmic granules and their generally segmented nuclei, will scatter light depending on their morphological complexity. A hypersegmented neutrophil will give an increased optical response with respect to a young neutrophil population which will be in the upper position of the optical axis depending on the presence of segmentation and/or granules.*

# SPECIMEN RUN & RESULTS

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# 1. INSTRUMENT START UP

## 1.1. Waste levels

• At the begenning of each day check if the waste container needs to be emptied. Becareful Wastes must be handled according to your local/national regulations.

• See *Chapter 5. Maintenance & Troubleshooting* to empty the waste container.

## 1.2. Printer start up

• Check the printer paper. If more printer paper is needed, replace the printer paper according to the *Printer user manual* supplied with the instrument.

• Press the ON/OFF switch. Check the control LEDs are ON.

• See *Chapter 4. Instrument configuration* to setup printing mode.

## 1.3. Pentra 60 C+ start up

**1-** Turn on the ***ABX WORKSTATION*** computer.

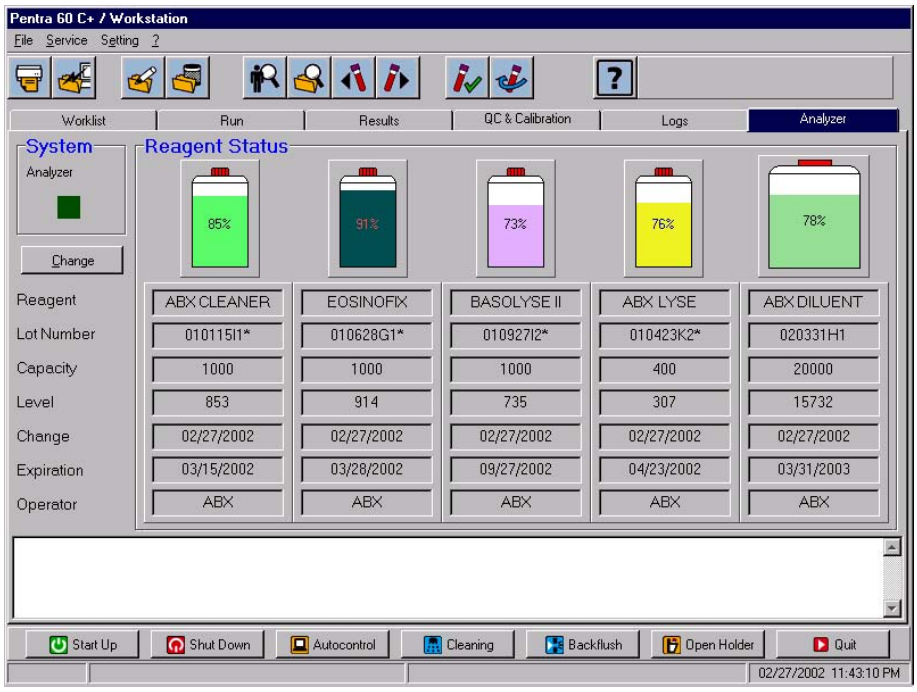
**2-** After computer boot press ALT+CTRL+DEL (or ALT+CTRL+SUPPR) to start a session & Start the Analyzer (On/Off switch located on the left side of the instrument)

**3-** Enter system password and wait until ***ABX WORKSTATION*** starts.

**IMPORTANT**

***The instrument will not operate if the reagent temperature is under 35°C (69°F). If required a bargraph is displayed after start up to check and wait for temperature progression.***

• *Analyzer indicator turns green if connection is succesfull and reagent levels are updated on the screen:*




• *Run a startup, click* Start Up *button.*

• *A rinse cycle is carried out,*

• *Then a background count (analysis cycle on reagent without blood specimen).*

• If the background counts are not within acceptable limits the message «**STARTUP FAILED**» is displayed.

***Background count limits:***

***WBC = 0.3 x10$^3$/mm$^3$***

***RBC = 0.03 x10$^6$/mm$^3$***

***Hgb = 0.3 g/dl***

***Plt = 7.0 x10$^3$/mm$^3$***

# 2. SPECIMEN COLLECTION AND MIXING

• All blood samples should be collected using proper technique.

***Consider all Specimens, Reagents, Calibrators, Controls, etc... that contain human blood or serum as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, Gloves, Lab coats, Safety glasses and/or Face shields, and follow other bio-safety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.***

• When collecting blood specimens, Venous blood is recommended, but Arterial blood may also be used in extreme cases. Blood collection must be placed in a Vacuum or atmospheric collection tubes.
For additional information on collecting venous and capillary blood samples, refer to NCCLS document H3-A4 and NCCLS document H4-A4 (sept 1999).

• The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collections will show a possible variation in the results.

## 2.1. Recommended anticoagulant

• The recommended anticoagulant is K3EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer.
K2EDTA is an acceptable alternative, as long as the sample collection is made in normal conditions.
Otherwise, blood clots may be possible.

## 2.2. Blood sample stability

• Specimens may be used between 15/20 minutes after collection. The results on all parameters depend on the mode of conservation of the sample.
Depending on the parameter to be measured, the sample stability may be upto 48 hours.

## 2.3. Microsampling

• The «Open tube» sampling mode enables the user to work with 100µl microsamples (for pediatrics and geriatrics).

## 2.4. Mixing

• The blood samples must be gently and thoroughly mixed just before placing them into the tube holder and closing the tube holder door. This will ensure a homogeneous mixture for measurement.

# 3. CALIBRATION VERIFICATION (CONTROL BLOOD SAMPLING)

• Before running specimens it is recommended that the operator runs a «Normal» control blood to verify that the system is within acceptable limits.

• The selection of the analysis mode (CBC/DIF) should be done according to the control used by the operator.

• For further informations please refer to *Chapter 4. Instrument configuration* to identify and enter new control blood lot.

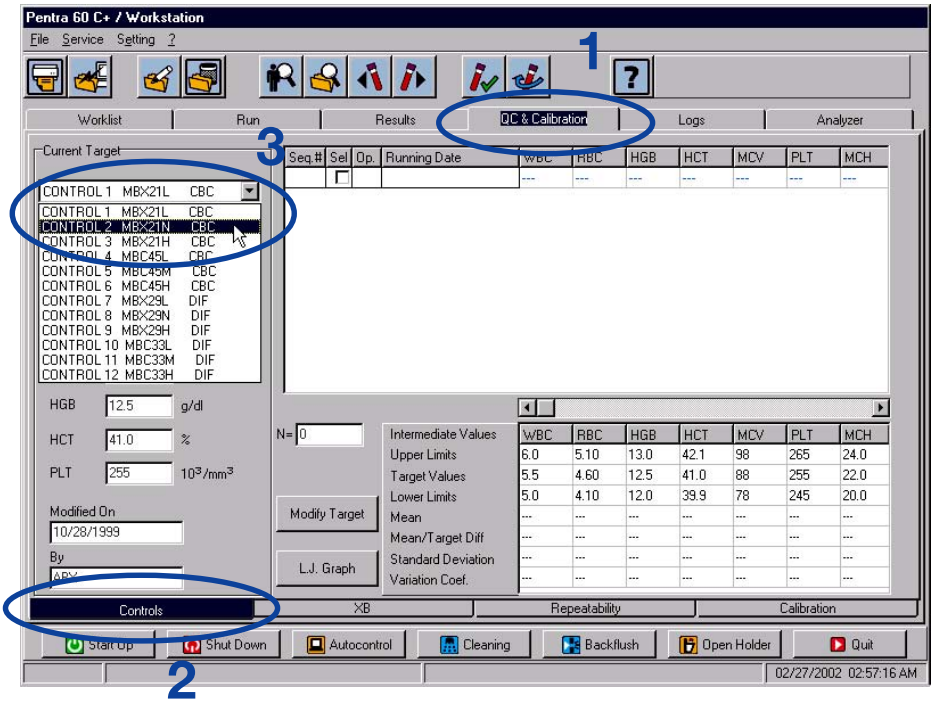
• Change the Lot number according to the Control blood you are going to use:

*1- Enter «**QC & Calibration**» Tab.*

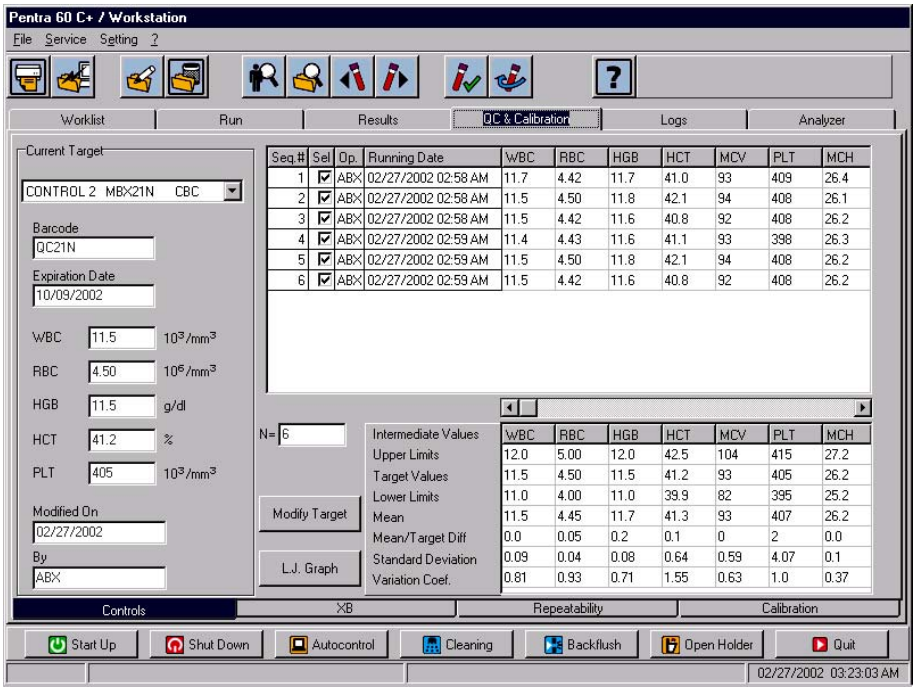
*2- Enter «**Controls**» Tab.*

*3- To select control blood lot: Open «**Current target**» scrolling list and click on the control blood lot you are going to use.*

*+ **If** the control blood is not listed please refer to Chapter 4. Instrument configuration.*



+ ***Previous*** *Controls ran with this lot are listed:*

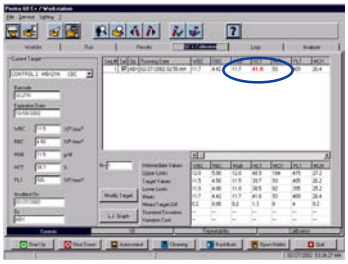

Pentra 60 C+ / Workstation
File Service Setting ?
Worklist
Run
Results
QC & Calibration
Logs
Analyzer
Current Target
CONTROL 2 MBX21N CBC
Barcode
QC21N
Expiration Date
10/09/2002
WBC 11.5 10³/mm³
RBC 4.50 10⁶/mm³
HGB 11.5 g/dl
HCT 41.2 %
PLT 405 10³/mm³
Modified On
02/27/2002
By
ABX
Modify Target
L.J. Graph
N= 6
Seq.# Sel Op. Running Date WBC RBC HGB HCT MCV PLT MCH
1 ABX 02/27/2002 02:58 AM 11.7 4.42 11.7 41.0 93 409 26.4
2 ABX 02/27/2002 02:58 AM 11.5 4.50 11.8 42.1 94 408 26.1
3 ABX 02/27/2002 02:58 AM 11.5 4.42 11.6 40.8 92 408 26.2
4 ABX 02/27/2002 02:59 AM 11.4 4.43 11.6 41.1 93 398 26.3
5 ABX 02/27/2002 02:59 AM 11.5 4.50 11.8 42.1 94 408 26.2
6 ABX 02/27/2002 02:59 AM 11.5 4.42 11.6 40.8 92 408 26.2
Intermediate Values WBC RBC HGB HCT MCV PLT MCH
Upper Limits 12.0 5.00 12.0 42.5 104 415 27.2
Target Values 11.5 4.50 11.5 41.2 93 405 26.2
Lower Limits 11.0 4.00 11.0 39.9 82 395 25.2
Mean 11.5 4.45 11.7 41.3 93 407 26.2
Mean/Target Diff 0.0 0.05 0.2 0.1 0 2 0.0
Standard Deviation 0.09 0.04 0.08 0.64 0.59 4.07 0.1
Variation Coef. 0.81 0.93 0.71 1.55 0.63 1.0 0.37
Controls
XB
Repeatability
Calibration
Start Up
Shut Down
Autocontrol
Cleaning
Backflush
Open Holder
Quit
02/27/2002 03:23:03 AM

- Prepare a «Normal» control blood according to the specific instructions detailed in the control blood package insert (temperature, mixing, etc...).
- Open the vial and locate it in the tube holder.
- In «***QC & Calibration\Controls***» Tab close the tube holder to start sampling.
- When the tube holder opens, remove and recap the vial.

## IMPORTANT

***Risk of erroneous results if the control blood is not continously mixed between each analysis. Continue mixing the control blood between each analysis.***

- When the analysis cycle ends, the result is displayed on the result chart table.
- Run the second calibrator sample when Green LED turns on.



***When control results are not within the acceptable ranges the parameter results are displayed in another color, perform the following:***

***1- Rerun the control,***

***2- Clean the system (see*** Chapter 5. Maintenance & Troubleshooting***) and run the control again,***

***3- Open a new vial,***

***4- Recalibrate the system as in «Recalibration».***

# 4. AUTO-CALIBRATION

**NOTE**

***If calibration verification (control blood sampling) has failed, perform an Auto-calibration. Use a MINOCAL Calibrator to calibrate the instrument.***

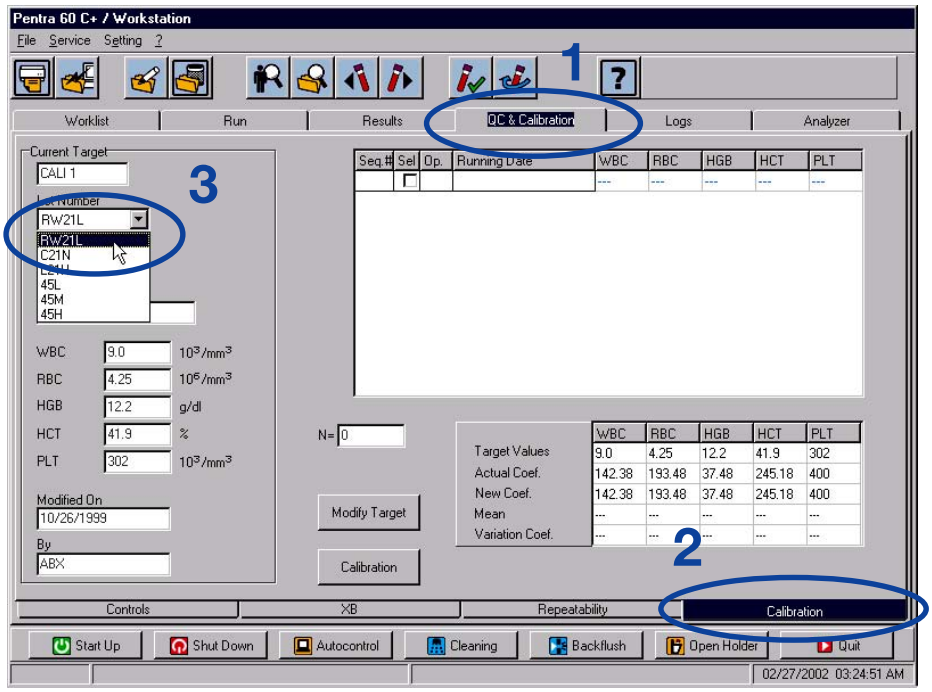
• *Change Calibrator Lot number according to the Calibrator you are going to use:*

*1- Enter «**QC & Calibration**» Tab.*

*2- Enter «**Calibrators**» Tab.*

*3- Select calibrator: Open «**Ident**» scrolling list and click on the calibrator you are going to use.*

+ ***If** the calibrator is not listed please refer to* Chapter 4. Instrument configuration.



- Prepare the calibrator according to the specific instructions detailed in the calibrator package insert (temperature, mixing, etc...).
- Open the vial and locate it in the tube holder.
- In «***QC & Calibration\Calibrators***» Tab close the tube holder.
- When the tube holder opens, remove and recap the vial.

**IMPORTANT**

***Risk of erroneous results if the calibrator is not continously mixed between each analysis. Continue mixing the calibrator between each analysis.***

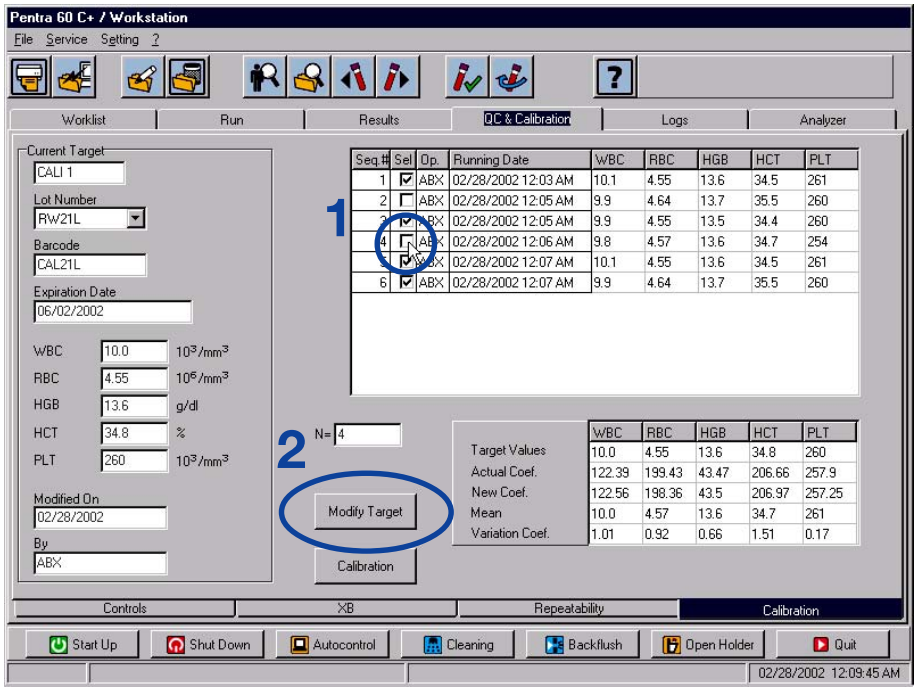
- When the analysis cycle ends, the first result is displayed on the result chart table.
- Run the second calibrator sample when Green LED turns on.

## IMPORTANT

***In order to obtain the best possible calibration, it is recommended to run at least 5 calibrator samplings.***

• *The calibration of the ABX PENTRA 60 C+ can be performed on 3 to 11 analyses.*

• *The auto-calculation module performs statistics on these results in order to obtain the best calibration coefficients.*



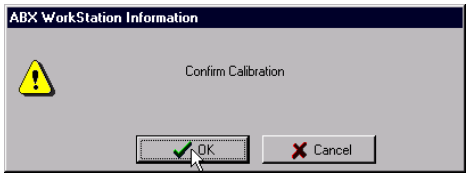

**1-** Select results to be involved in the statiscal calculation by clicking checked box in «**Sel**» column.

• To discard a result from the statiscal calculation click again in checked box to remove the mark.

• The instrument calculates the statistical calibration factors for each parameter.

**2-** If the Coefficient of variation is within the limits setup as described *Chapter 4. Instrument configuration* and the percentage difference between the target and the mean value is less than 20, instrument will allow auto-calibration: Click on Calibration to update new calibration coefficients.

• Confirm the changement by clicking OK in the following dialog box:



# 5. WORKLIST

## 5.1. Worklist description

- The purpose of the worklist (*Worklist tab*) is to build the list of analyses to be performed and to view all the previous performed analyses.
- The worklist groups,list all the information (fields of the *Worlist tab*) relating to an analysis (patient) file.
- Description of the Worklist's fields:

Seq.# — Sequence number, automatically incremented by the software, is the chronologic number of specimen sampling and is unique.

Sample ID — After capture, the field is compared to the list of Reserved numbers corresponding to the analyses: Control, Calibration or Repeatability. If the number corresponds, the entry is completed automatically, changes to blue and becomes non-modifiable. The Identification field takes the name of the target corresponding to a Control, Calibration or Repeatability blood. If it does not correspond, it will be searched for among already performed analyses, a link is proposed on the existing patient.
If it is not found, it is searched for among analyses to be performed. It is rejected if it already exists: this is the guarantee of unicity for analyses that have not been performed.
Otherwise, this identification number is accepted (16 characters max.)

Patient Name — Name of the patient: A combo box detects and propose to duplicate an already listed Patient name or to separate it as an another Patient name (30 characters max.).

Patient Number — Number given to a patient, no detection of duplications (16 characters max.).

Test — Choose type of the analysis: Swap between DIF and CBC mode using SPACE or ENTER key, or use the combo box. Default type is DIF mode.

Department — Input patient blood sampling location, choose from one dynamic list or add a new name (10 characters max.).

Birth date — Patient date of birth (MM/DD/YYYY).

Age — Age is automatically updated with the patient date of birth.

Gender — Choose from one predetermined combo box list: M, F or Blank.

Type — Allows to specify blood profile: Standard, Male, Female, Child... (Default is standard). Use the combo box to choose between types. See *Chapter 4. Instrument configuration* to define blood types.

Physician — Input physician name, choose from one dynamic list or add a new name (17 characters max.).

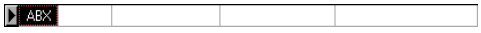
Collect date — Date and Time of blood collection in MM/DD/YYYY-HH:MM.

Op. — Operator field is automatically updated by the code of the operator who starts the instrument. (not operational at this time)

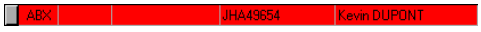
Comment — Use this field to enter comments (50 characters max.).

- Worklist color sheme:

A white line (free or not) shows a routine analysis to be run (create a new line with Add new entry, , icon):




A red highlighted line shows the sample running at the time:




A green highlighted line shows a routine analysis completed:

A blue highlighted line shows a cycle such as QC, Callibration or Repeatability, not performed:

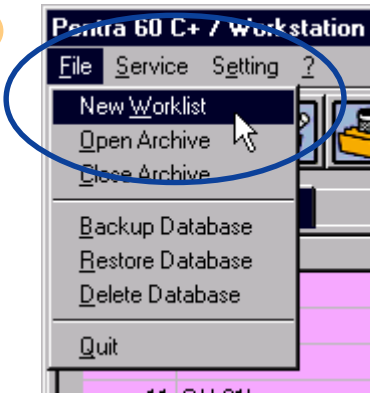
A pink highlighted line shows a perfomed service cycle:

## 5.2. Creating a new Worklist

- To create a new Worklist open File menu and select New Worklist option:

**NOTE**

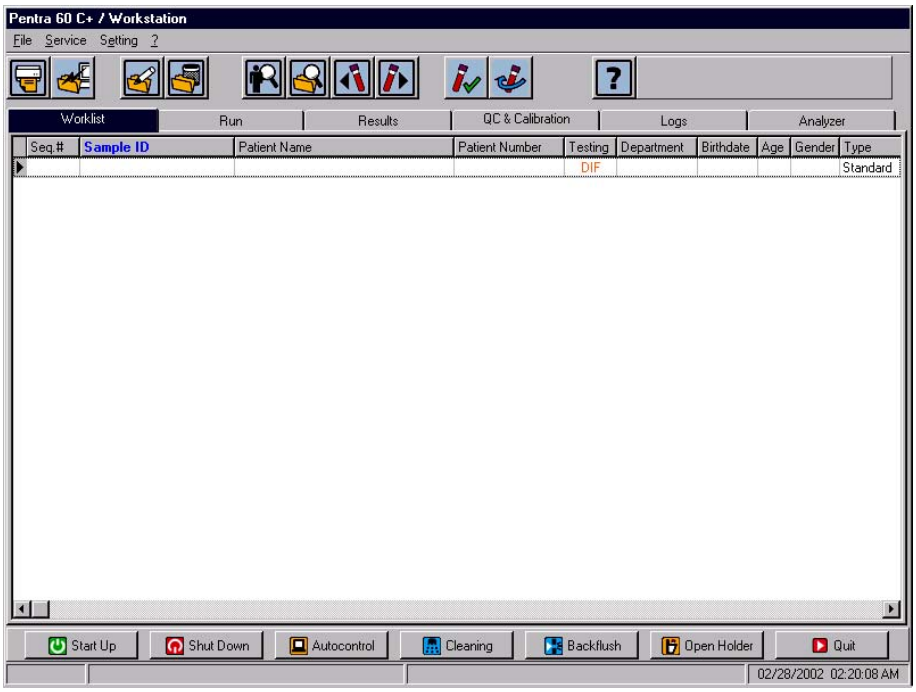
***When a new Worklist is created the previous Worklist is automatically stored as an archive file.***




**NOTE**

***It is recommended to create a new Worklist everyday.***

- An empty Worklist is opened:



## 5.3. Worklist edition

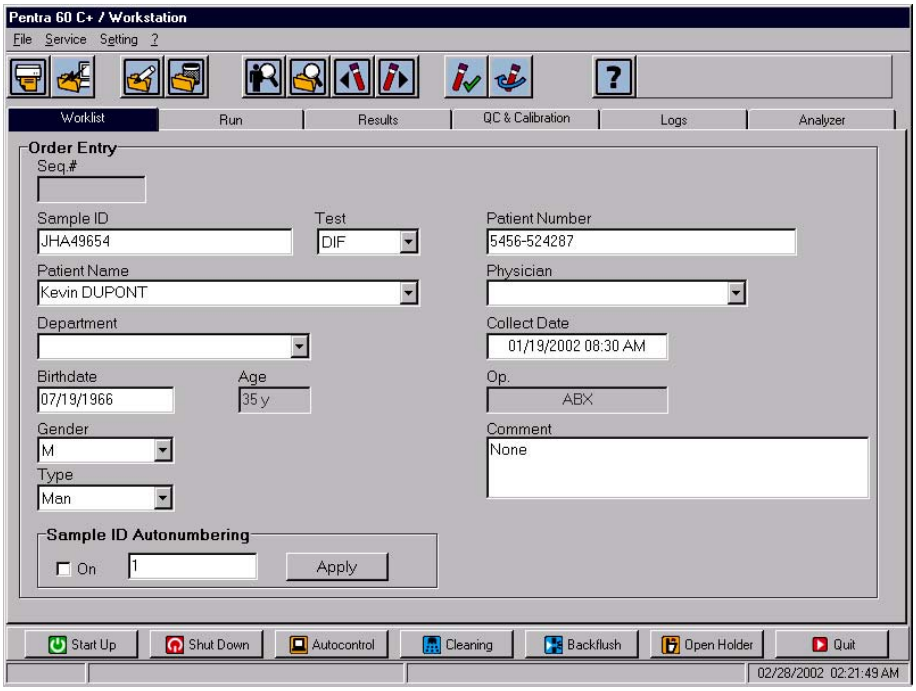
NOTE

***If you run a sample without creating a patient file, a line will be automatically added at the end of the Worklist with default values and cannot be modified.***

• To create a new patient file from the worklist, or from the «***Patient file***» window: Click «***Add new entry***», , icon, a line is added at the end of the workllist, or a new patient file is opnened (you can use icon in tool bar to swap between «***Worklist***» and «***Patient file***» windows).

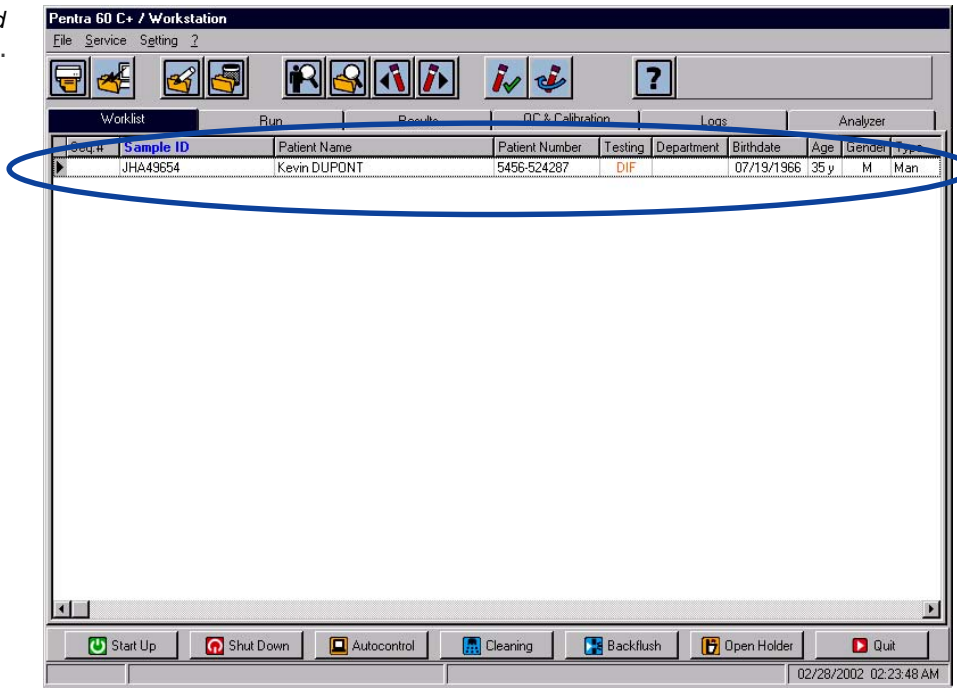
• From the «***Patient file***» window capture patient's datas:

+ ***Use*** *TAB key to move from one field to another, SPACE or ENTER key to swap between positions.*



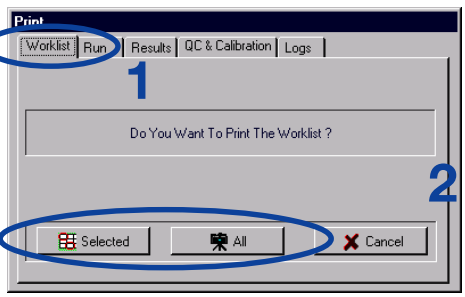
• In the worklist the new file is shown as follow:

+ ***See** Worklist's keyboard shortcuts in the* Annex.


Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Seq.# Sample ID Patient Name Patient Number Testing Department Birthdate Age Gender Type
JHA49654 Kevin DUPONT 5456-524287 DIF 07/19/1966 35 y M Man
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
02/28/2002 02:23:48 AM

## 5.4. Worklist printout

• *Click toolbar* *icon, or «**Menu\File\Printer**», to open «**Printer**» dialog box:*



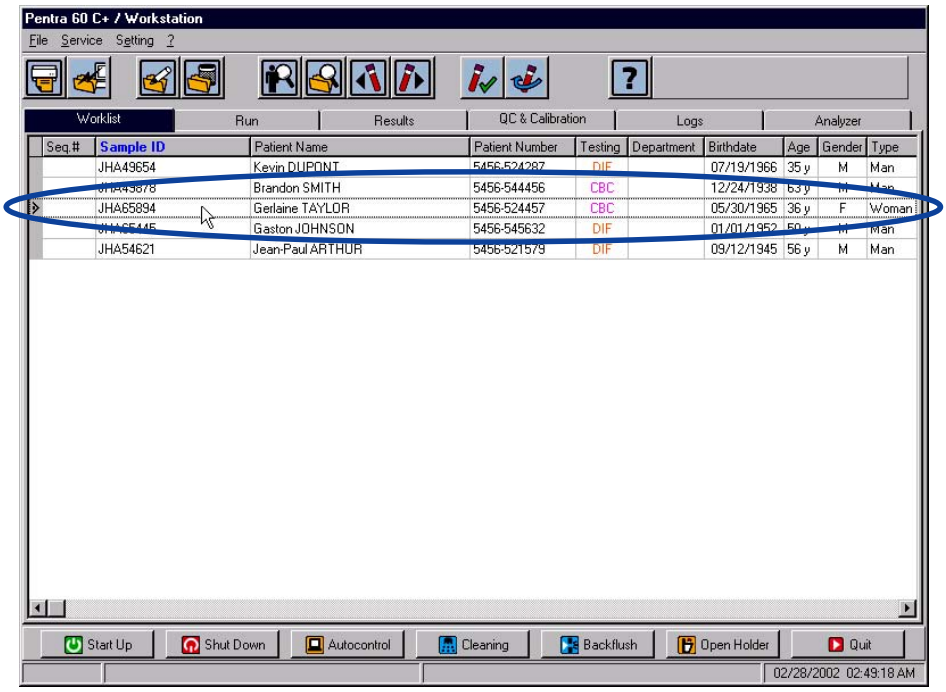

***1-*** Enter «***Worklist***» Tab.

***2-*** Click button to print only selected worklist lines (patient line selection + CTRL key), or button to print all the worklist lines.

# 6. RUNNING SPECIMENS

• The specimen to be run is the first selected line in the Worklist or, if no line is selected, the line following last specimen ran or the first.

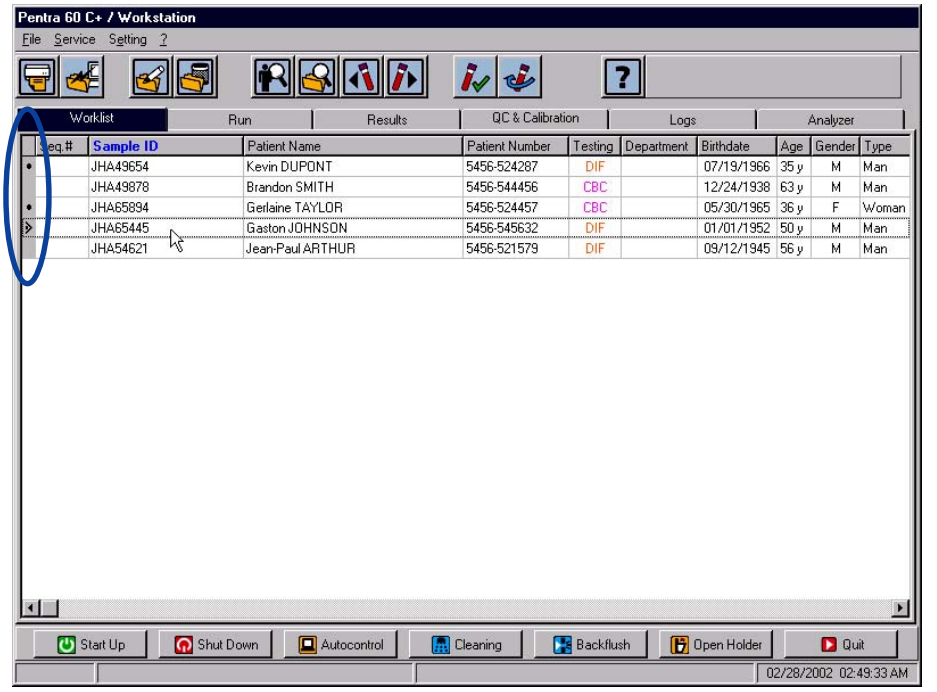
+ ***If*** *you want to run a particular specimen, click the line holding CTRL key: the line is selected and the icon* » *appears in the lefthand column.*


Pentra 60 C+ / Workstation
File Service Setting ?
Worklist
Run
Results
QC & Calibration
Logs
Analyzer
Seq.# Sample ID Patient Name Patient Number Testing Department Birthdate Age Gender Type
JHA49654 Kevin DUPONT 5456-524287 DIF 07/19/1966 35 y M Man
JHA49878 Brandon SMITH 5456-544456 CBC 12/24/1938 63 y M Man
JHA65894 Gerlaine TAYLOR 5456-524457 CBC 05/30/1965 36 y F Woman
JHA65445 Gaston JOHNSON 5456-545632 DIF 01/01/1952 50 y M Man
JHA54621 Jean-Paul ARTHUR 5456-521579 DIF 09/12/1945 56 y M Man
Start Up
Shut Down
Autocontrol
Cleaning
Backflush
Open Holder
Quit
02/28/2002 02:49:18 AM

## NOTE

***This specimen will be the next to be run.***

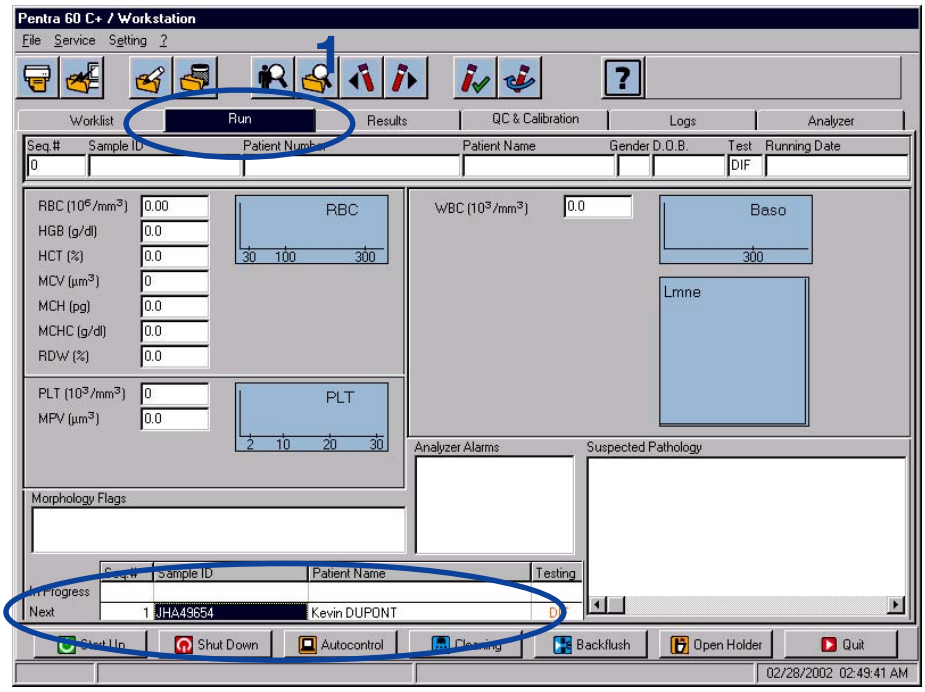
+ ***If*** *you want to run several particular specimens, click all the different lines holding CTRL key, the lines are selected, the icon* • *appears in the lefthand column (except for the first).*


Pentra 60 C+ / Workstation
File Service Setting ?
Worklist
Run
Results
QC & Calibration
Logs
Analyzer
Seq.# Sample ID Patient Name Patient Number Testing Department Birthdate Age Gender Type
JHA49654 Kevin DUPONT 5456-524287 DIF 07/19/1966 35 y M Man
JHA49878 Brandon SMITH 5456-544456 CBC 12/24/1938 63 y M Man
JHA65894 Gerlaine TAYLOR 5456-524457 CBC 05/30/1965 36 y F Woman
JHA65445 Gaston JOHNSON 5456-545632 DIF 01/01/1952 50 y M Man
JHA54621 Jean-Paul ARTHUR 5456-521579 DIF 09/12/1945 56 y M Man
Start Up
Shut Down
Autocontrol
Cleaning
Backflush
Open Holder
Quit
02/28/2002 02:49:33 AM

## NOTE

***Worklist selected patient lines are the next specimens to be run (from the top to the end of the list).***

*1- Enter «**Run**» Tab.*




*• The next specimen to be run is shown in «**Run**» tab, field «**Next**»:*

## IMPORTANT

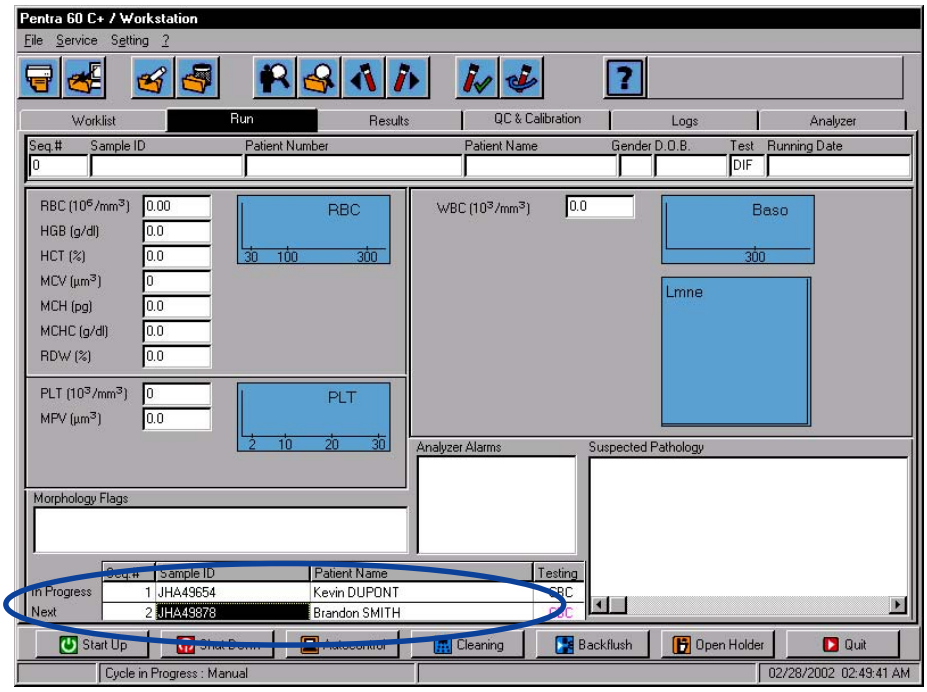
***Blood specimen must be thoroughly and gently mixed (with a gentle up and down and rolling motion), before any measurement.***

*• Present the specimen as shown on the diagram to the right. When green LED is litten, close tube holder door to start sampling.*

*• When tube holder opens remove the tube. When the LED turns to green again the instrument is ready for the next analysis.*

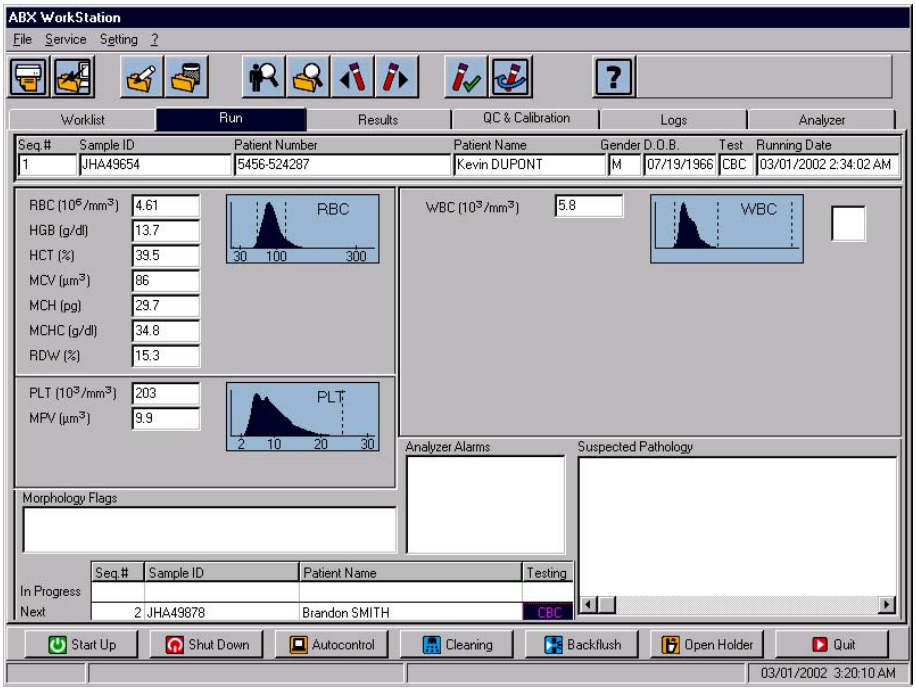
*+ **LEDs** flash during specimen aspiration.*

• *«**Run**» tab shows during analysis of the specimen in progress («**In progress**» field) and the sample coming next («**Next**» field):*

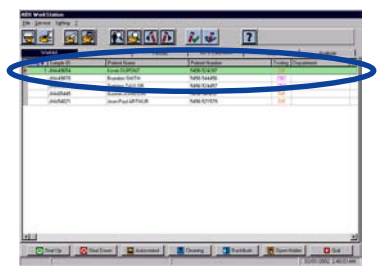

Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Seq.# Sample ID Patient Number Patient Name Gender D.O.B. Test Running Date
RBC (10⁶/mm³) HGB (g/dl) HCT (%) MCV (µm³) MCH (pg) MCHC (g/dl) RDW (%)
PLT (10³/mm³) MPV (µm³)
WBC (10³/mm³)
RBC PLT Baso Lmne
Analyzer Alarms
Suspected Pathology
Morphology Flags
Seq.# Sample ID Patient Name Testing
In Progress 1 JHA49654 Kevin DUPONT CBC
Next 2 JHA49878 Brandon SMITH CBC
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
Cycle in Progress : Manual
02/28/2002 02:49:41 AM

\+ ***In** Worklist the actual specimen running is highlighted in red:*

• *At the end of the analysis, «**Run**» tab displays the results for the last specimen:*


ABX WorkStation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Seq.# Sample ID Patient Number Patient Name Gender D.O.B. Test Running Date
1 JHA49654 5456-524287 Kevin DUPONT M 07/19/1966 CBC 03/01/2002 2:34:02 AM
RBC (10⁶/mm³) 4.61
HGB (g/dl) 13.7
HCT (%) 39.5
MCV (µm³) 86
MCH (pg) 29.7
MCHC (g/dl) 34.8
RDW (%) 15.3
PLT (10³/mm³) 203
MPV (µm³) 9.9
WBC (10³/mm³) 5.8
RBC PLT WBC
Analyzer Alarms
Suspected Pathology
Morphology Flags
Seq.# Sample ID Patient Name Testing
In Progress
Next 2 JHA49878 Brandon SMITH CBC
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
03/01/2002 3:20:10 AM

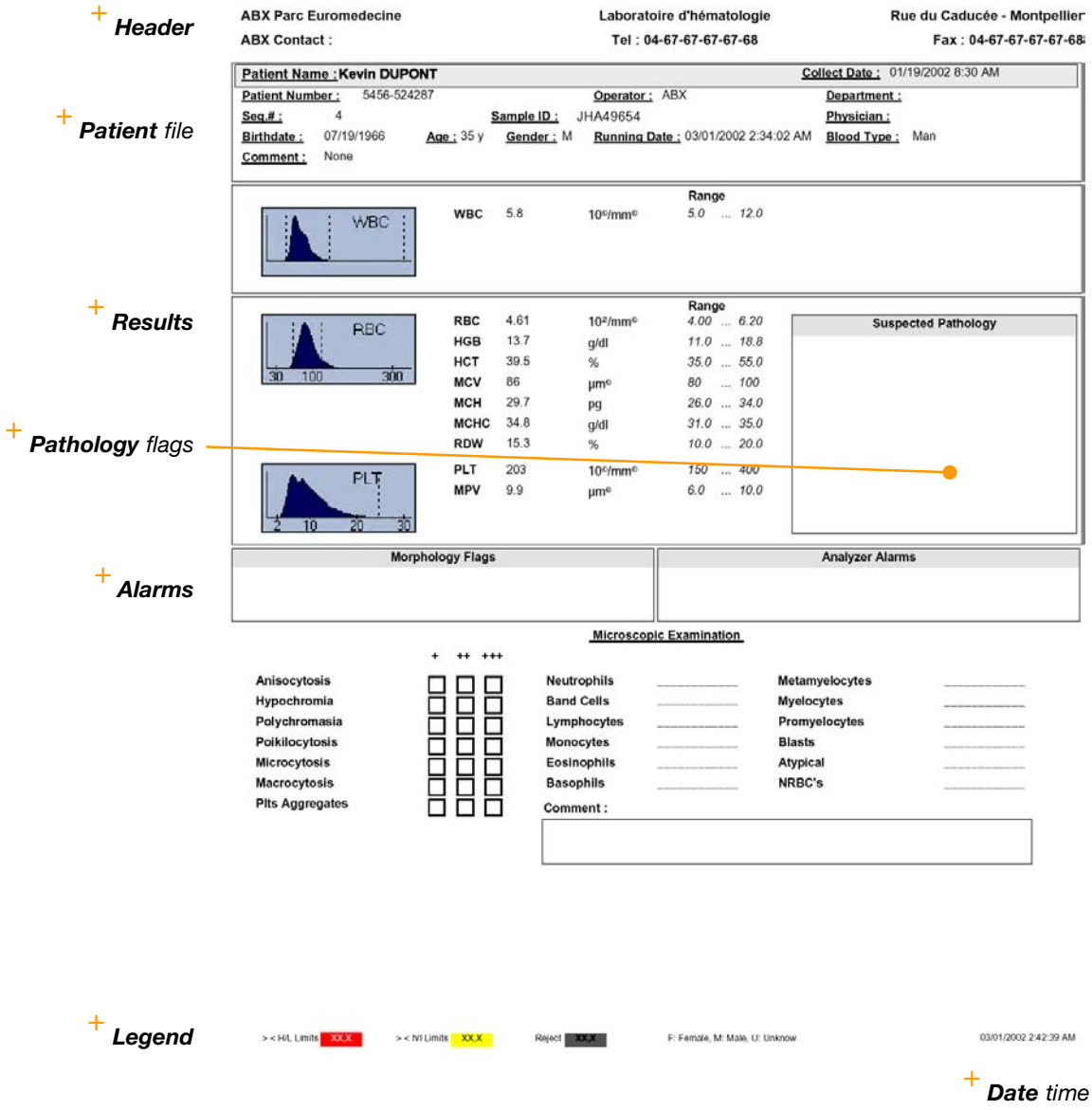
\+ ***In** Worklist, the line corresponding to the ran specimen has been highlighted in green:*



# 7. RESULTS

## 7.1. CBC Mode

### 7.1.1. Print output



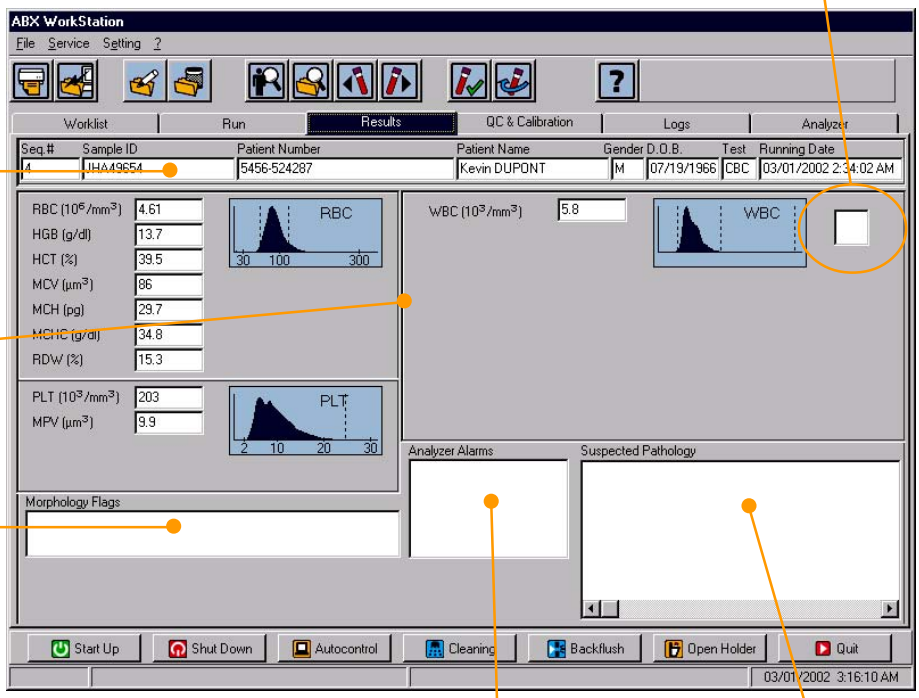
## 7.1.2. Result tab

+ ***The** result is not validated*

+ ***Patient** file*

+ ***CBC** Results & Histograms*

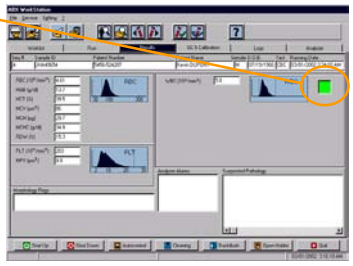
+ ***Morphology** flags*



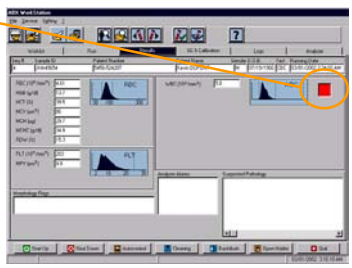

+ ***Instrument** alarms*

+ ***Pathology** flags*

+ ***The** result is validated*

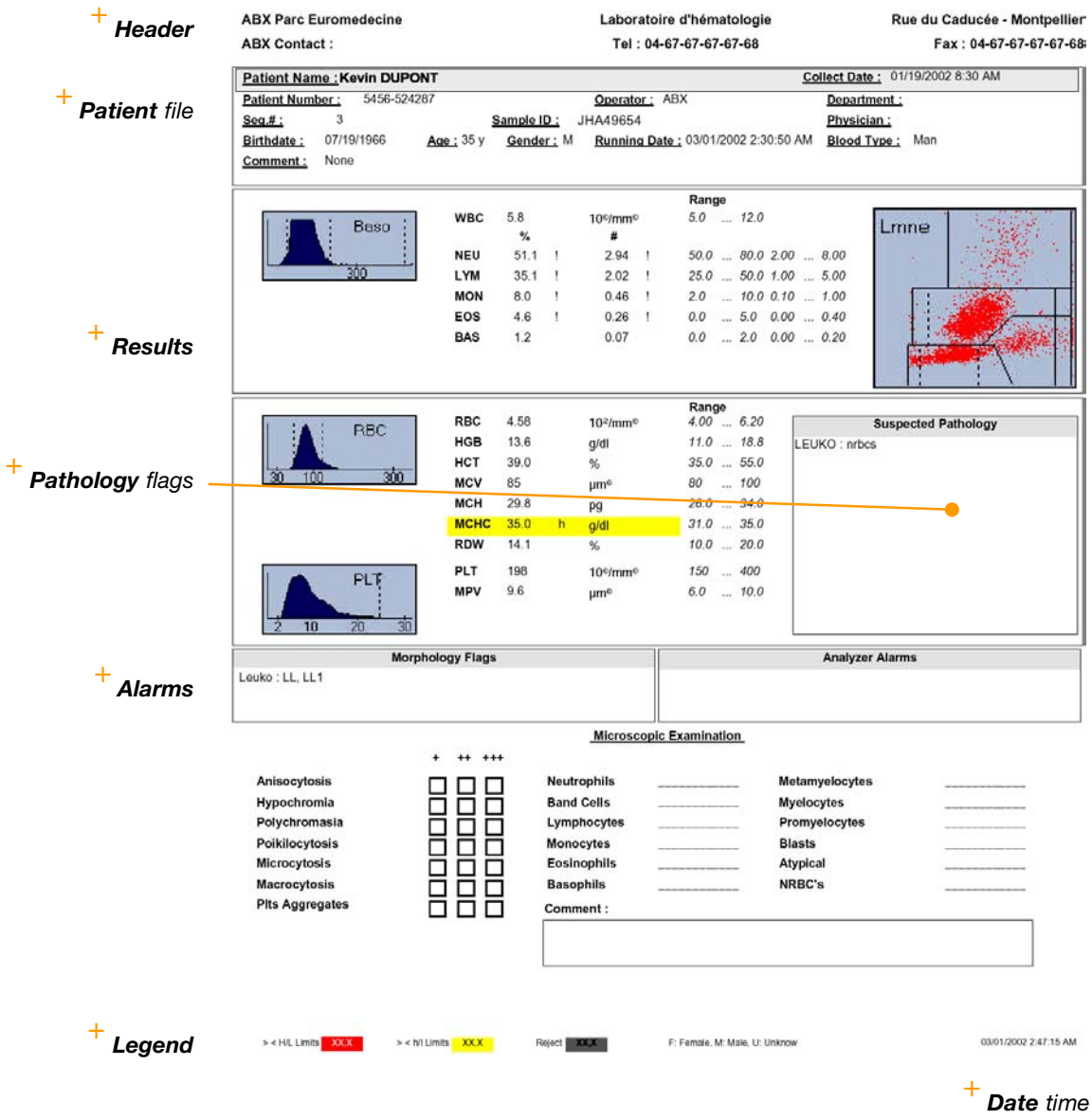


+ ***The** rerun option has been selected for this sample. The specimen line is duplicated in the worklist and will be the next sample to be run*

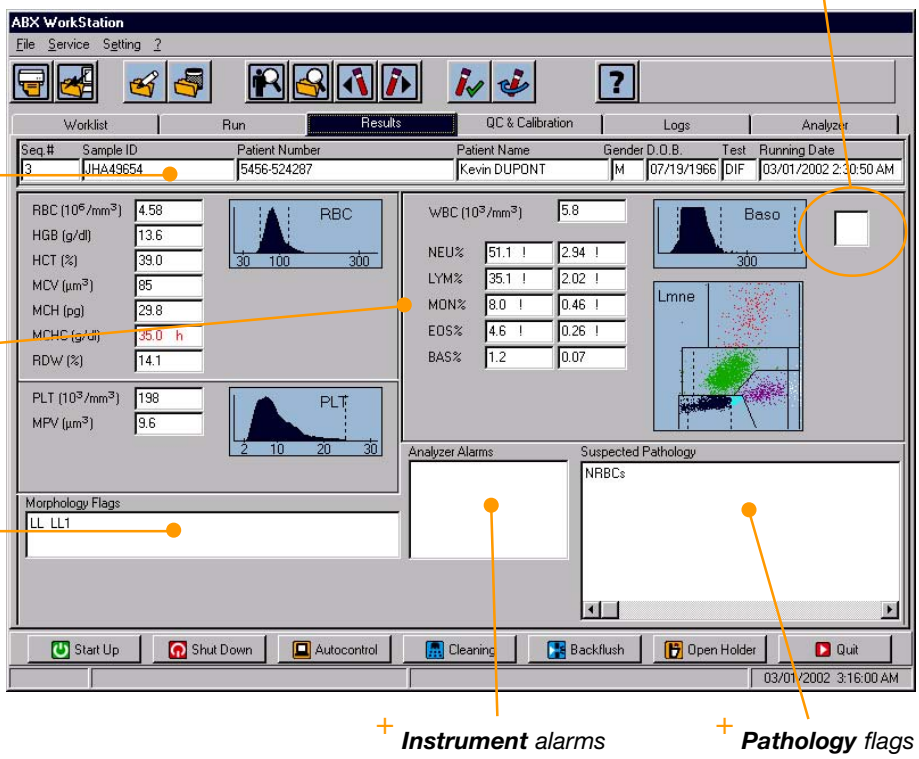


## 7.2. 5DIFF Mode

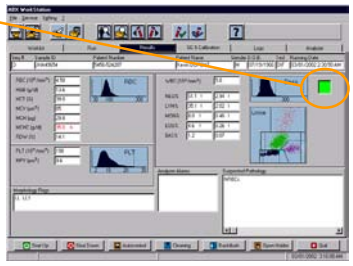
### 7.2.1 Print output



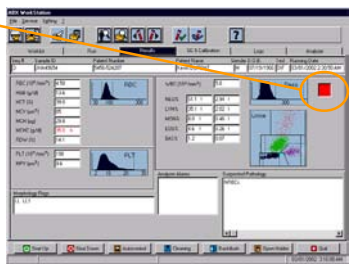
## 7.2.2. Result tab




+ **The** *result is validated*

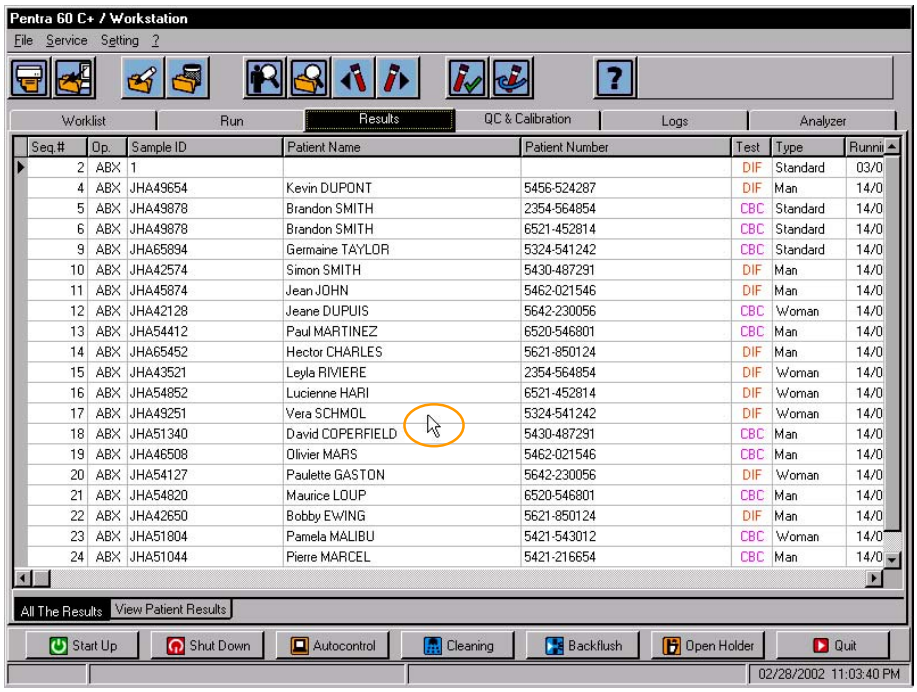


+ **The** *rerun option has been selected for this sample. The specimen line is duplicated in the worklist and will be the next sample to be run*

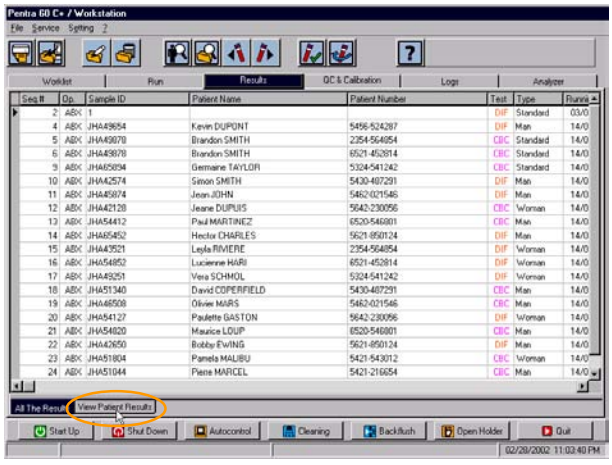


## 7.3. «Results» tab in List mode

• To select and display one result from the list, double click over the «**Results**» tab to display the «**All The Results**» tab, then, double click over the result in the list to display it:

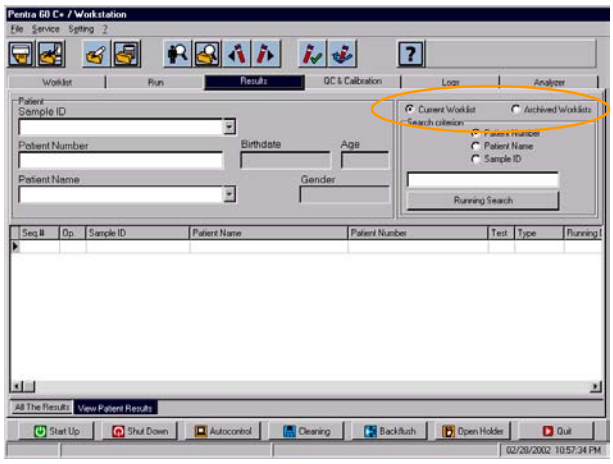

Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
Seq.# Op. Sample ID Patient Name Patient Number Test Type Runni
2 ABX 1 DIF Standard 03/0
4 ABX JHA49654 Kevin DUPONT 5456-524287 DIF Man 14/0
5 ABX JHA49878 Brandon SMITH 2354-564854 CBC Standard 14/0
6 ABX JHA49878 Brandon SMITH 6521-452814 CBC Standard 14/0
9 ABX JHA65894 Germaine TAYLOR 5324-541242 CBC Standard 14/0
10 ABX JHA42574 Simon SMITH 5430-487291 DIF Man 14/0
11 ABX JHA45874 Jean JOHN 5462-021546 DIF Man 14/0
12 ABX JHA42128 Jeane DUPUIS 5642-230056 CBC Woman 14/0
13 ABX JHA54412 Paul MARTINEZ 6520-546801 CBC Man 14/0
14 ABX JHA65452 Hector CHARLES 5621-850124 DIF Man 14/0
15 ABX JHA43521 Leyla RIVIERE 2354-564854 DIF Woman 14/0
16 ABX JHA54852 Lucienne HARI 6521-452814 DIF Woman 14/0
17 ABX JHA49251 Vera SCHMOL 5324-541242 DIF Woman 14/0
18 ABX JHA51340 David COPERFIELD 5430-487291 CBC Man 14/0
19 ABX JHA46508 Olivier MARS 5462-021546 CBC Man 14/0
20 ABX JHA54127 Paulette GASTON 5642-230056 DIF Woman 14/0
21 ABX JHA54820 Maurice LOUP 6520-546801 CBC Man 14/0
22 ABX JHA42650 Bobby EWING 5621-850124 DIF Man 14/0
23 ABX JHA51804 Pamela MALIBU 5421-543012 CBC Woman 14/0
24 ABX JHA51044 Pierre MARCEL 5421-216654 CBC Man 14/0
All The Results View Patient Results
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
02/28/2002 11:03:40 PM

• To find one result in the worklist or in the archived lists, click over the «**View Patient Results**» tab:

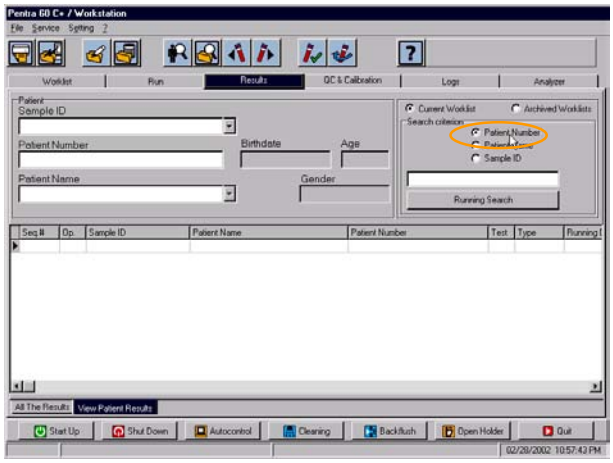


NOTE

***Research is done on results that have a «Patient Name» field unempty (Even if the criterions are Patient Number or Sample ID).***

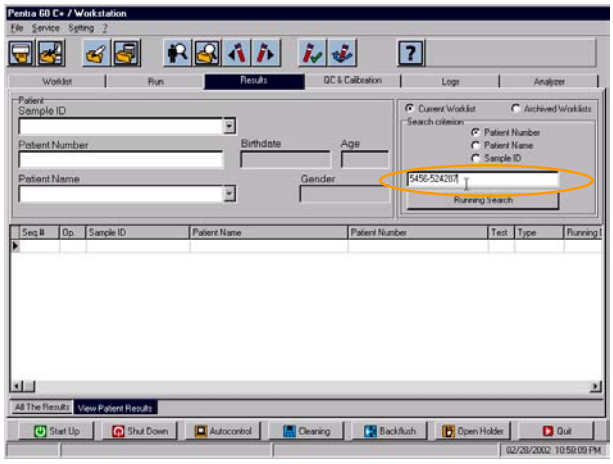



• Select the research over the Current worklist or over the Archived worklists.



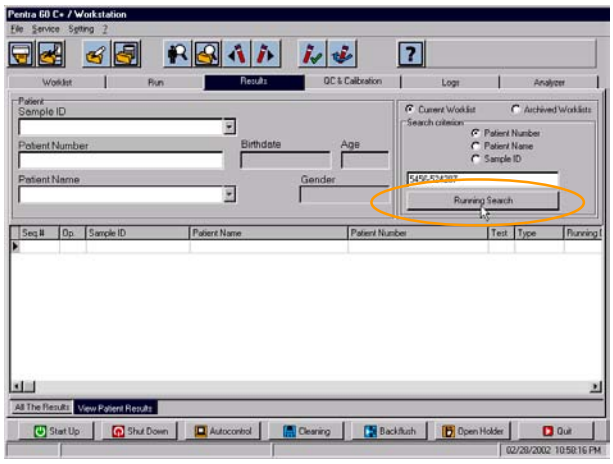

• Select the criterion used for the research:

Patient Number
Patient Name
Sample ID



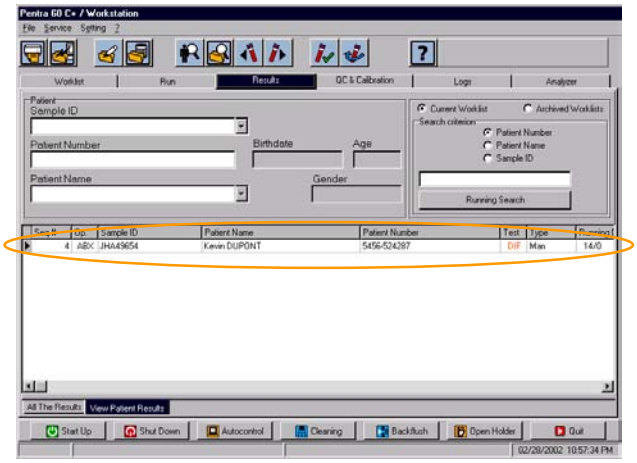

• Enter your research object.

(Exemple: Patient Number = 5456-524287)




- Start the research by clicking over the button

Running Search.




- If the research is succeed, the result is displayed:

## 7.4. Flags

These flags can be divided up into 5 different groups:
- Flags linked to a result when it exceeds the normality limits.
- Flags linked to a problem in the morphology of blood cell population.
- Flags linked to a result or to instrument operation leading to a «default analysis».
- Flags linked to instrument in use.

NOTE

***Each flag sensitivity can be adjusted by the operator (see Chapter 4. Instrument configuration)***

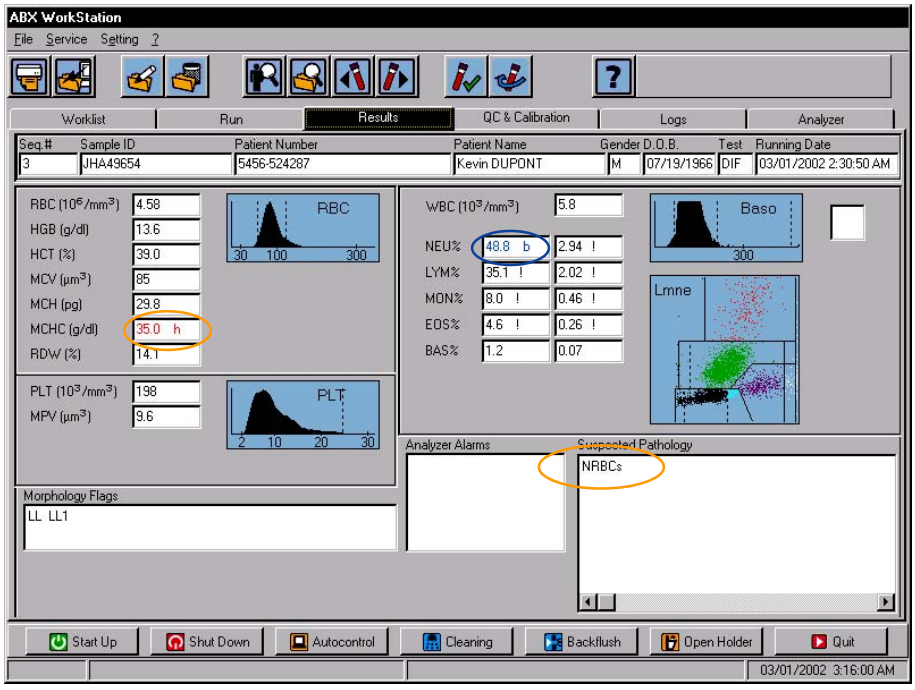
### 7.4.1. Normal and panic ranges

*«**h**» indicates that the result is above the normal limit set by the user.*

*«**l**» indicates that the result is below the normal limit set by the user.*

*«**H**» indicates that the result is above the panic limit set by the user.*

*«**L**» indicates that the result is below the panic limit set by the user.*




+ ***These** flags may be criteria for the pathology messages.*

## 7.4.2. Flags giving an analysis default

Different alarms can be activated if a parameter result exceeds instrument capacity:

- Result forced to 0,
- Replaced by ----,
- Result assiocated with an asterisk (*) or exclamation mark (!)

***Results exceeding instrument capacity***

| PARAM. | CONDITIONS | CONSEQUENCES |
|---|---|---|
| WBC | > 120x10³/µL | WBC replaced by ---- D |
| | > 150x10³/µL | Diff # results replaced by ---- |
| WBC | < 0x10³/µL | Diff results replaced by ---- |
| and | | No WBC flag occurs |
| | | No WBC/Baso histogram |
| RBC | < 0.1x10⁶/µL | No LMNE matrix |
| RBC | ≤ 0.01x10⁶/µL | RDW, MCV, MCH, MCHC, RBC forced to 0 |
| | | No RBC histogram |
| Hgb | < 0.7 g/dL | Hgb forced to 0 |
| | < 2 g/dL | MCH, MCHC foced to 0 |
| Hct | < 0.7 % | Hct forced to 0 |
| | > 80 % | Hct replaced by ---- D |
| MCV | < 10 fL | RDW replaced by ---- |
| | > 199 fL | MCV replaced by ---- |
| Plt | < 5.0x10³/µL | MPV, Pct, PDW replaced by ---- |
| | | No SCL flag occurs |
| | | No Plt histogram |
| PDW | MIC flag | PDW replaced by ---- |
| | or SCL flag | |
| | or Plt < 5.0x10³/µL | |
| Pct | SCL flag | Pct replaced by ---- |
| | or Plt < 5.0x10³/µL | |
| MPV | SCL flag | MPV replaced by ---- |
| | or Plt < 5.0x10³/µL | |

NOTE

***Use the instrument diluent to dilute the sample if a ---- D flag occurs on WBC or Hct.***

***Hgb blank***

+ ***See*** Chapter 4. Instrument configuration *to defined BHB# and MHB %.*

• At the end of the Startup cycle, the Hgb blank value is controlled. If this value is not within acceptable limits, a reject flag (shown by *****) is triggered on the Hgb parameter.

• On each analysis cycle, the instrument performs a Hgb blank on diluent and checks this measured against the Hgb reference value.
If this Hgb blank value is too different from the mean of the reference values of previous analyzes (higher than BHB# defined by the user) the instrument triggers a suspiscion flag (shown by **!**) on the Hgb parameter.

• (**!**) is also associated with Hgb result if the difference between 3 successive measures on the same sample is higher than MHB % limit defined by the user.

• Sample has to be rerun.

NOTE

***No result will be given on Hgb [(----) instead] when 3 suspicion flags (!) associated with the Hgb reference value have been triggered off (MCHC and MCH are also not reported).***

***Reject (between two counts)***

• A reject flag (shown by *****) occurs when two counts on a parameter differ more than the pre-defined limits. It indicates that the result is not coherent and the sample has to be rerun.

• ***RBC***
A reject on RBC gives a default analysis value, shown by a * on RBC, MCV, MCH, MCHC and RDW.

• ***Plt***
A reject on Plt gives a default analysis value, shown by a * on Plt, Pct, MPV and PDW.

• ***WBC***
A reject on WBC gives a default analysis value, shown by a * on WBC and Diff # results.

## 7.4.3. LMNE matrix flags

***Suspiscion***

• When populations are detected in abnormal quantity in one or several boxes of the matrix, some flags may occur associated with (**!**).
If one result appears with one or several parameters associated with this (**!**), the result should be further investigated (pathology suspiscion, clotted sample, plasma cells...).

• Twelve different flags may occur regarding the shifting of leukocyte populations on the matrix channel or the presence of abnormal populations.
These flags are: **Reject, NO, LL, LL1, NL**, **MN, RM, LN, RN, NE, ALY, GCI** (see flag signification further in this *Chapter*).

***Reject (on LMNE matrix)***

• A reject on the LMNE channel indicates a poor correlation between the resistive and the optical measurements on the matrix.
It is shown by a (*) on all the differential parameters in % and #.

• The result is not reliable and specimen must be rerun.

***NO flag***

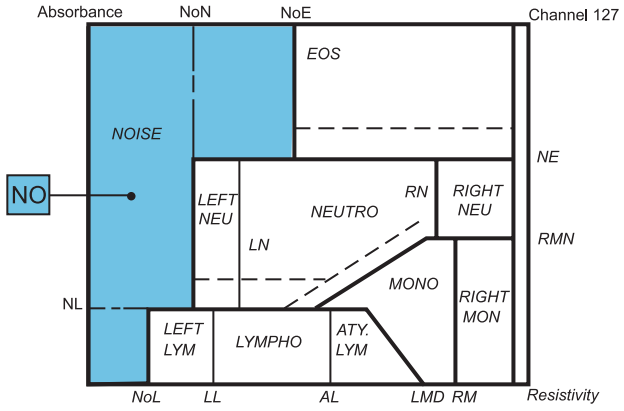
Meaning: Background **NO**ise.

This flag occurs when the number of particles counted in the background noise area is higher than the limit set up in **NO#** or when the number of counted particles versus the total number of WBC, is above the **NO%** limit.

Suspected abnormalities:
- Platelet aggregates,
- Large number of platelets,
- Erythrocyte membrane resistant to lysis (stroma),
- NRBCs,
- Pollution.

+ ***Standard** values for **NO**:*
*%100*
*#120*

*Adjustment:*
*see* Chapter 4. Instrument configuration




NOTE

***This alarm is displayed in the «Analyzer Alarm» area on the result ticket.***

***LL flag***

Meaning: **L**eft **L**ymphocytes

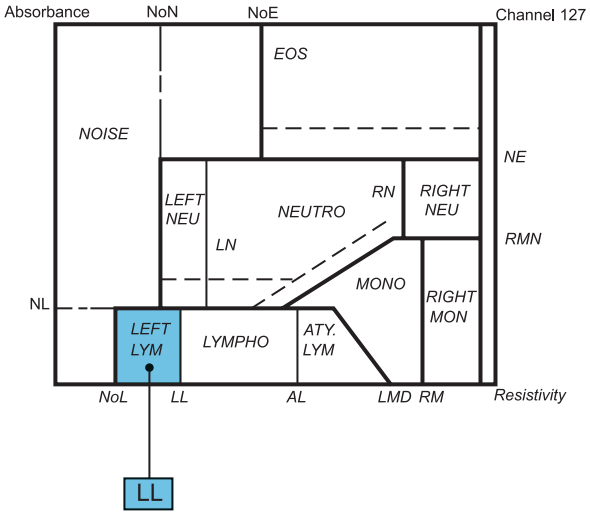
Presence of a significantly large popu-lation on the left-hand side of the lympho-cyte area. This flag appears when the number of particles counted is higher than the limit set up in **LL#** or when the number of counted particles versus the total number of WBC exceeds the **LL%** limit.

Suspected abnormalities:
- Small lymphocytes,
- Platelets aggregates,
- NRBCs,
- Erythrocyte membrane resistant to lysis (stroma).

This flag occurs associated with an (**!**) on:
- LYM % LYM #
- NEU % NEU #
- MON % MON #
- EOS % EOS #
- ALY % ALY #
- LIC % LIC #

+ ***Standard** values for **LL**:*
*% 100*
*# 50*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***LL1 flag***

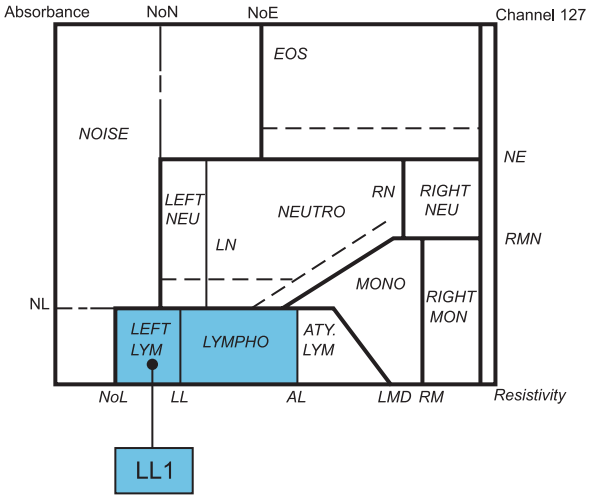
Meaning: **L**eft **L**ymphocytes **1**

Presence of a significantly large population of cells on the left-hand side of the lymphocytes area. This flag occurs when the number of particles counted is higher than the limit set up in **LL1# *and*** when the number of particles counted in **LL** regarding to the total number of lymphocytes is above the **LL1%** limit.

Suspected abnormalities:
- Platelet aggregates,
- NRBCs,
- Erythrocyte membrane resistant to lysis (stroma),
- Stroma,
- Small abnormal lymphocytes.

+ ***Standard** values for **LL1**:*
*% 5*
*# 45*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***NL flag***

Meaning: **N**eutro/**L**ympho

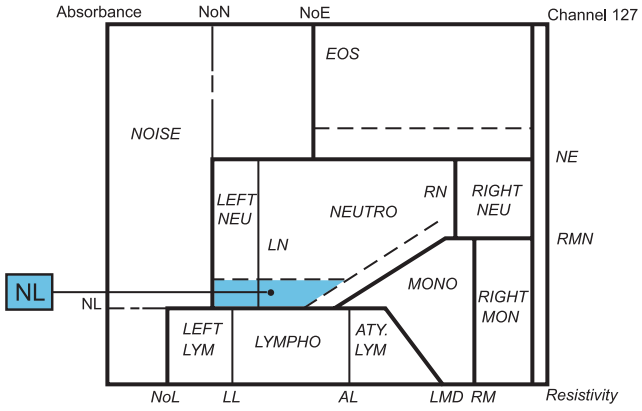
Presence of a significantly large population of cells located in the separation threshold area between lymphocytes and neutrophils. This flag occurs when the number of particles counted in this area is higher than the limit set up in **NL#**, or when the number of counted particles regarding to the total number of WBC is above **NL%** limit.

Suspected abnormalities:
- Small neutrophils without granules and/or slightly segmented,
- Lymphocytes with a segmented nucleus or Activated Lymphocytes,
- Neutrophils with membrane weakness.

This flag occurs associated with an (**!**) on:
- LYM %  LYM #
- NEU %  NEU #

+ ***Standard*** *values for* ***NL****:*
*% 3*
*# 120*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***MN flag***

Meaning: **M**ono/**N**eutro

Presence of a significantly large population of cells located in the separation threshold area between monocytes and neutrophils. This flag occurs when the number of particles counted in this area is higher than the limit set up in **MN#** or the number of particles counted in MN versus the total number of WBC is above the **MN%** limit.

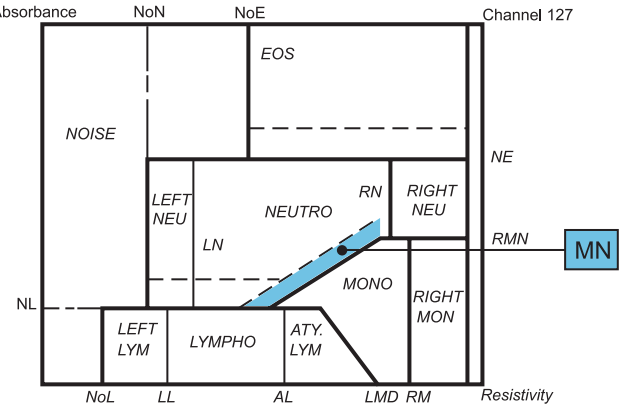
Suspected abnormalities:
- Monocytes having granules in their cytoplasm or hyperbasophilic monocytes,
- Young neutrophils with non-segmented nuclei (bandcells).

This flag occurs associated with an (**!**) on:
- ALY % ALY #
- LIC % LIC #

and replaces:
- NEU %, NEU #, MON %, MON # by ----

+ ***Standard** values for **MN**:*
*% 100*
*# 120*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***LN flag***

Meaning: **L**eft **N**eutro

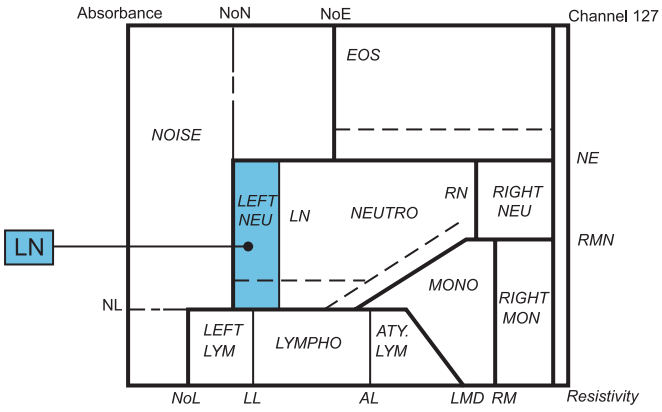
Presence of a significantly large population of cells located on the lefthand side of the neutrophil area. This flag occurs when the number of particles counted in this area is higher than the limit setup in **LN#** or when the number of particles counted regarding the total number of WBC is above **LN%** limit.

Suspected abnormalities:
- Neutrophil destruction due to incorrect storage of the sample or an old sample,
- Contamination, stroma or platelet aggregates.

This flag occurs associated with an (**!**) on all WBC differencial parameters.

+ ***Standard*** *values for* ***LN****:*
*% 2.5*
*# 999*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***NE flag***

Meaning: **N**eutro/**E**osino.

Presence of a significantly large population of cells located in the separation area between neutrophils and eosinophils because of a superimposition of the 2 populations. This flag occurs when the number of particles counted in this area is higher than the limit setup in **NE#** or when the number of particules counted regarding the total number of WBC is above the **NE%** limit.

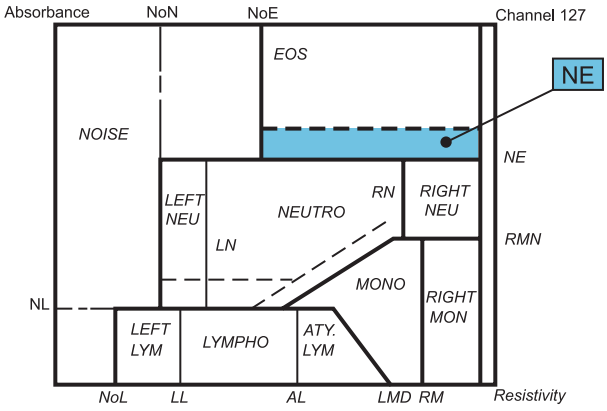
Suspected abnormalities:
- Young eosinophils,
- Giant hypersegmented neutrophils,
- Eosinophils with low intracytoplasmic material,
- Immature cells.

This flag is associated with an (**!**) on:
- LIC %  LIC #

and replaces:
- NEU %, NEU #, EOS %, EOS # by ----

+ ***Standard** values for **NE**:*
*% 1.1*
*# 60*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***ALY flag***

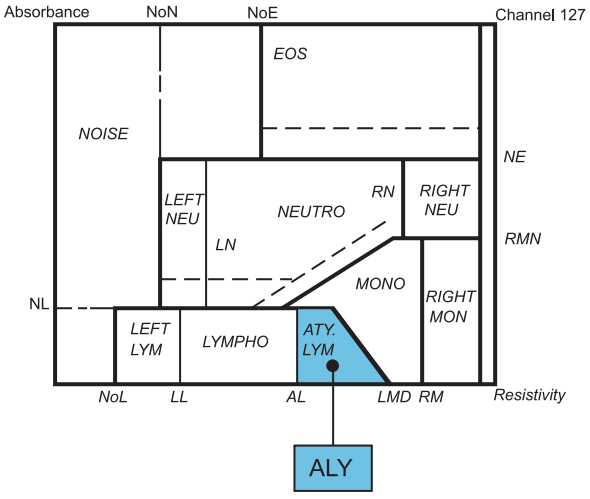
Meaning: **A**typical **L**ymphocytes

Presence of a significantly large population of cells located on the righthand side of the Lymphocytes area. This flag occurs when the number of particles counted in this area is higher than the limit setup in **ALY#** or when the number of particles counted regarding the total number of WBC is above the **ALY%** limit.

Suspected abnormalities:
- Large Lymphocytes,
- Reactive Lymphoid forms,
- Stimulated lymphocytes,
- Plasmocytes.

+ ***Standard** values for **ALY**:*
*% 2*
*# 0.2*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***RM flag***

Meaning: **R**ight **M**ono

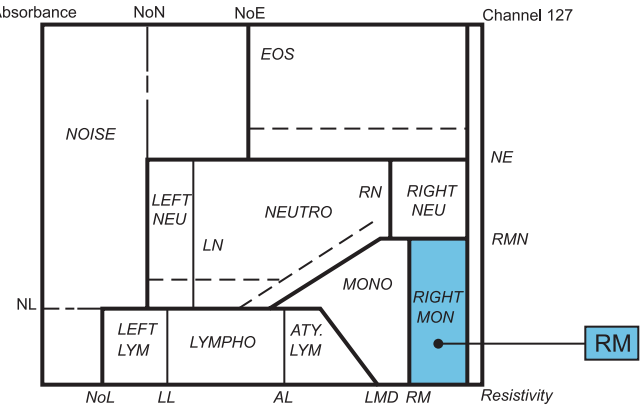
Presence of a significantly large population of cells located on the righthand side of the monocyte area (low LIC). This flag occurs when the number of particles counted in this area is higher than the limit setup in **RM#** or when the counted particles regarding the total of WBC is above **RM%** limit.

Suspected abnormalities:
- Large monocytes,
- Hyperbasophilic monocytes,
- Myelocytes or promyelocytes,
- Large blasts.

This flag occurs associated with an (**!**) on:
- NEU % NEU #
- MON % MON #
- LIC % LIC #

+ ***Standard** values for **RM**:*
*% 1.1*
*# 999*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***RN flag***

Meaning: **R**ight **N**eutro

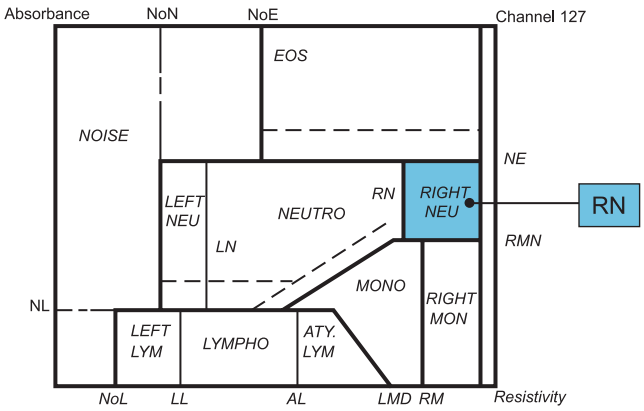
Presence of a significantly large population of cells located on the righthand side of the neutrophil area (high LIC). This flag occurs when the number of particles counted in this area is higher than the limit setup in **RN#** or when the number of particles counted regarding the total number of WBC is above the **RN%** limit.

Suspected abnormalities:
- Large neutrophils,
- Immature cells from granulocyte hemopoiesis (metamyelocytes, myelocytes, promyelocytes).

This flag is associated with an (**!**) on:
- NEU %  NEU #
- LIC %  LIC #

+ ***Standard** values for **RN**:*
*% 1.1*
*# 999*

*Adjustment:*
*see* Chapter 4. Instrument configuration



***LIC flag***

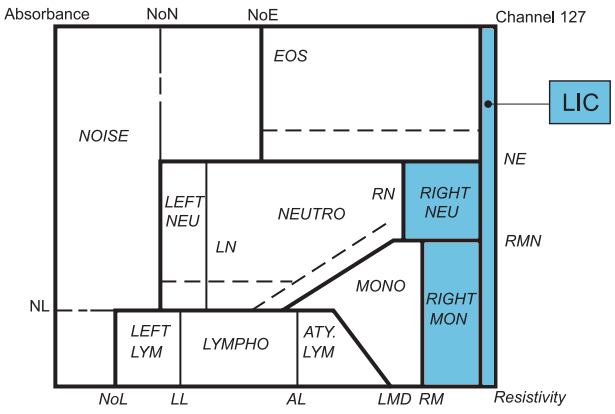
Meaning: **L**arge **I**mmature **C**ells

Presence of a significantly large population of cells located on **RN** + **RM** + **channel 127** areas. This flag occurs when the number of particles counted in this area is higher than the limit set up in **LIC#**, or when the number of counted particles regarding to the total number of WBC is above the **LIC%** limit.

Suspected abnormalities:
- Large monocytes,
- Hyper basophilic monocytes,
- Myelocytes, Metamyelocytes, Promyelocytes,
- Large Blasts,
- Large Neutrophils.

+ ***Standard** values for **LIC**:*
*% 2*
*# 0.2*

*Adjustment:*
*see* Chapter 4. Instrument configuration



## 7.4.4. Flags on WBC/BASO histogram

***CBC and DIFF Mode***

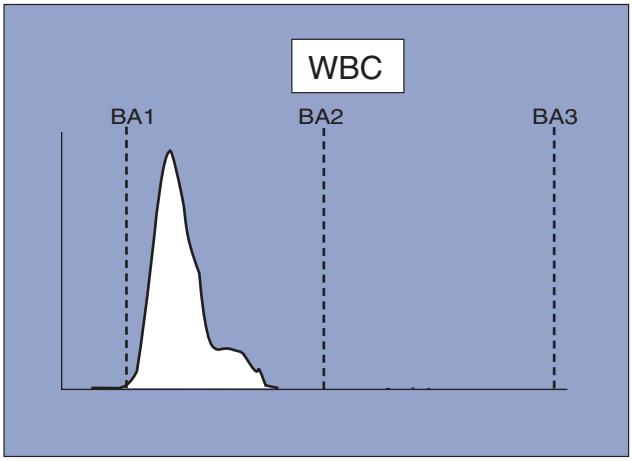
**L1** flag is established according to the ratio of the cells counted between the 0 channel and BA1.

**L1** indicates the presence of an abnormal number of cells in comparison with leukocytes.

Suspected abnormalities:
- Plt aggregates,
- NRBCs.

+ ***Standard*** *values for* ***L1****:*
*% 3*
*# 200*

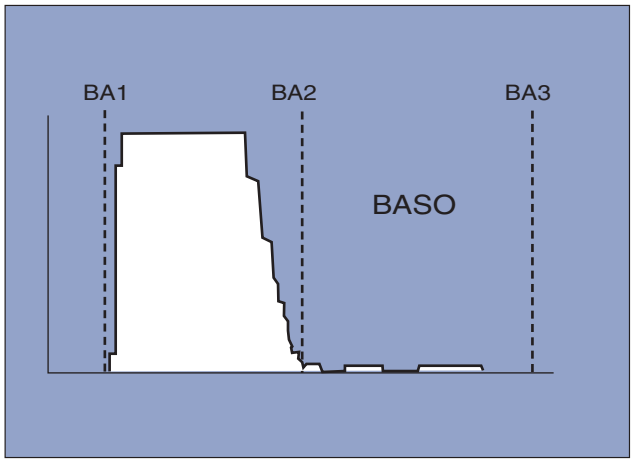
*Adjustment:*
*see* Chapter 4. Instrument configuration



***DIFF mode only***

**MB** (Meaning: **M**ono **B**aso)
This flag occurs when the percentage of basophils found in the Baso channel is above the percentage of Lympho/Mono/Neutro raw counts found on the matrix channel.

**BASO+**
If the BASO % exceeds 50 %, a **BASO+** flag is generated.
The Basophils are not taken away from the matrix populations and ---- is displayed instead of the BAS % and BAS #.




NOTE

***The BASO+ flag is displayed in the «Analyzer Alarm» area on the result ticket.***

## 7.4.5. Flags on RBC histogram

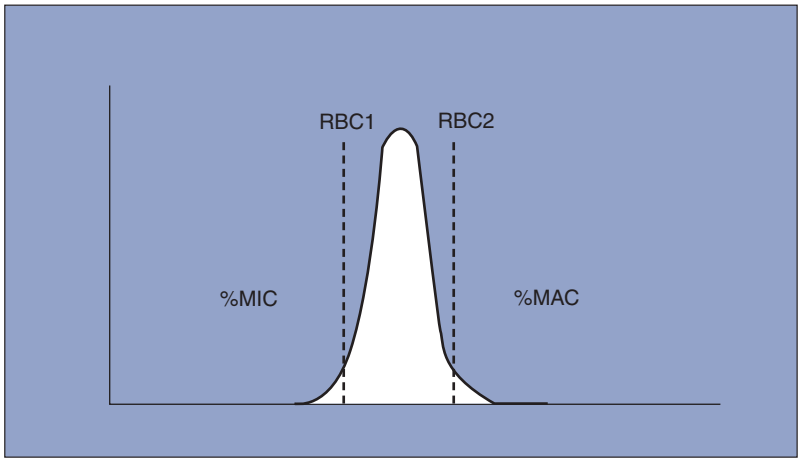
***MIC & MAC flags***

**MIC** and **MAC** flags are generated when the percentage of cells counted in the microcytic area (MIC) and macrocytic area (MAC) compared to the total number of RBCs are above the limits set up by user.

• RBC1 and RBC2 thresholds define the microcytic and macrocytic areas and are calculated according to the MCV and the RDW.

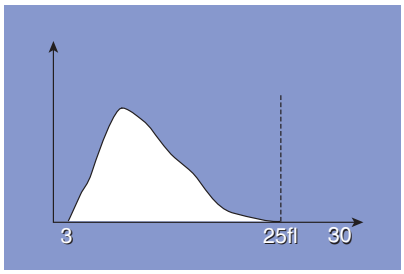
+ ***Standard*** *values for* ***Mic****: %5*
***Mac****:%45*

*Adjustment:*
*see* Chapter 4. Instrument configuration



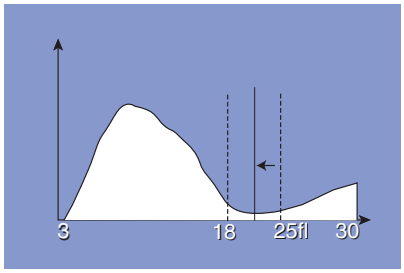
## 7.4.6. Flags on Plt histogram

• The Plt histogram has 256 channels between 2fL and 30fL. A mobile threshold (at 25 fL by default) moves according to the microcytic RBCs present in the platelet analysis area.

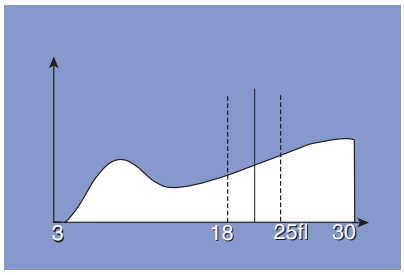



• The Plt flags are generated under the following conditions:

+ ***An*** *excessive presence of particles on the right side of the threshold area (after 25 fL) will generate the* ***MIC*** *(****Mic****rocytes) flag (shown in the platelet alarm area). In this case the mobile threshold looks for a valley between 18fL and 25fL (standard area).*



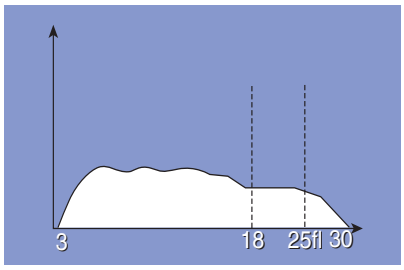

+ ***When*** *the mobile threshold can not be positioned in the standard area (from 18fL to 25fL), a* ***Plt*** *reject (*) and a* ***MIC*** *flag are generated. The Plt result is not reliable. Verify the result using a Platelet Rich Plasma (PRP) or a manual count.*




+ ***If*** *the mobile threshold cannot be positioned (no valley between the Plt and RBC histograms) the* ***SCH*** *(****Sch****izocytes) flag is generated.*

***Suspected abnormalities:***
- *Presence of schizocytes*
- *Presence of Platelet aggregates,*

*check the result on a slide.*




+ **SCL** (**S**mall **C**e**l**l) indicates the presence of small cells in the 2fL and 3fL zone. A second analysis should be carried out and the results verified.

### 7.4.7. WBC balance

+ ***WBC Balance*** *can be activated or deactivated: see* Chapter 4. Instrument configuration

Control of the injected volume in the optical flowcell allows a second count of the WBC.

The two counts are compared, if the difference between both counts is higher than a defined threshold (depending of the quantity measured), a **LMNE+** or a **LMNE-** flag is generated.

• WBC count is within 0 and 2501:
If the WBC LMNE count is higher than 50% of the WBC BASO count, a **LMNE+** flag is generated.
If the WBC LMNE count is lower than 50% of the WBC BASO count, a **LMNE-** flag is generated.

• WBC count is within 2501 and 8000:
If the WBC LMNE count is higher than 20% of the WBC BASO count, a **LMNE+** flag is generated.
If the WBC LMNE count is lower than 20% of the WBC BASO count, a **LMNE-** flag is generated.

• WBC count is higher than 8000:
If the WBC LMNE count is higher than 15% of the WBC BASO count, a **LMNE+** flag is generated.
If the WBC LMNE count is lower than 15% of the WBC BASO count, a **LMNE-** flag is generated.

The WBC BASO channel is considered as a reference and is used to calibrate the WBC LMNE channel. The ratio calculated between the two channel calibration coefficients is, except technical intervention, stable. In any case it is the WBC BASO result that is reported.

NOTE

***The WBC balance flags (LMNE+ and LMNE-) shall not be triggered if and only if:***
***•The test selected is «CBC».***
***•The WBC Balance option is not activated.***

***These flags are associated with an (!) on all differential parameters (% and #).***
***L1 flag is associated with an (!) on WBC value and on absolute values of the differential parameters.***

## 7.5. Pathology messages

• Pathology suspicion messages may be displayed and printed out. Triggering conditions are linked to the laboratory limits entered by the user.

**WARNING**

***These messages indicate a possible pathological disorder and should be used to assist with quick and efficient screening of abnormal samples and for diagnosis. It is recommended to use suitable reference methods to confirm diagnoses.***

**NOTE**

***There is no pathological message in the following cases:***

- ***On WBC: For a WBC < 0.1x10³mm³ or WBC > 91.3x10³/mm³. or for a counting reject (Except if an Erythroblast flag is the NUCLEATED RBC).***
- ***On RBC: For a counting reject or an RBC value < 0.1x10⁶/mm³.***
- ***On Plt: For a counting reject or a Plt value < 5x10³/mm³.***

### 7.5.1. WBC messages

*«H»: high extreme limit*

*«L»: low extreme limit*

| Message | Triggering Condition |
|---|---|
| LEUKOCYTOSIS | WBC > WBC H |
| LEUKOPENIA | WBC < WBC L |
| LYMPHOCYTOSIS | * LYM # > LYM # H or if LYM % > LYM % H |
| LYMPHOPENIA | * LYM # < LYM # L or if LYM % < LYM % L |
| NEUTROPHILIA | * NEU # > NEU # H or if NEU % > NEU % H |
| NEUTROPENIA | * NEU # < NEU # L or if NEU % < NEU % L |
| EOSINOPHILIA | * EOS # > EOS # H or if EOS % > EOS % H |
| MYELEMIA | NEU % > NEU % H and LIC # > LIC # H |
| LARGE IMMATURE CELL | LIC # > LIC # H or LIC % > LIC % H |
| ATYPIC LYMPHOCYTE | ALY # > ALY # H or ALY % > ALY % H |
| LEFT SHIFT | (MN or NL) and RN |
| NUCLEATED RBC | LL |
| MONOCYTOSIS | * MON # > MON # H or if MON % > MON % H |
| BASOPHILIA | * BAS # > BAS # H or if BAS % > BAS % H |
| BLASTS | BAS # > BAS # H and LIC # > LIC # H and RM |

** means the pathology is detected, firstly, on the high and low absolute values of the corresponding parameter.*

### 7.5.2. RBC messages

*«H»: high extreme limit*

*«L»: low extreme limit*

| Message | Triggering Conditions |
|---|---|
| ANEMIA | Hgb < Hgb L |
| ANISOCYTOSIS | RDW > RDW H |
| MICROCYTE | on MIC flag |
| MICROCYTE+ | % MIC > 10 % |
| MICROCYTE++ | % MIC > 15 % |
| MACROCYTE | on MAC flag |
| HYPOCHROMIA | MCHC < MCHC L |
| COLD AGGLUTININ | MCHC > MCHC H and WBC < 91.3x10³/mm³ |
| MICROCYTOSIS | MCV < MCV L |
| MACROCYTOSIS | MCV > MCV H |
| ERYTROCYTOSIS | RBC > RBC H |

### 7.5.3. Plt messages

*«H»: high extreme limit*

*«L»: low extreme limit*

| Message | Triggering Conditions |
|---|---|
| THROMBOCYTOSIS | Plt > Plt H |
| THROMBOCYTOPENIA | Plt < Plt L |
| MICROCYTOSIS<br>SCHIZOCYTE<br>SMALL CELL | See Triggering conditions for these flags in paragraph ***Flags on RBC curve*** |
| Plt AGGREGATE (1) | Plt < 150x10³/mm³ + WBC Reject or<br>NO + PDW > 20 or<br>NO + MPV > 10 or<br>NO + Plt < 150x10³/mm³ or<br>NO + WBC Reject or<br>L1 or LL1 + PDW > 20 or<br>L1 or LL1 + MPV > 10 or<br>L1 or LL1 + Plt < 250x10³/mm³ |
| ERYTHROBLASTS (2) | LL or WBC reject + L1 or WBC reject + LL1 |
| ERYTHROBLASTS<br>Plt AGGREGATE | (1) and (2) are false + (L1 or LL1 or WBC reject) |
| MACROPLATELETS | MPV > 11 |

### 7.5.4. Miscellaneous

*«H»: high extreme limit*

*«L»: low extreme limit*

| MESSAGE | TRIGGERING CONDITION |
|---|---|
| PANCYTOPENIA | WBC < WBC L<br>and RBC < RBC L<br>and Plt < Plt L |

## 7.6. Analyzer alarms

***Total rejection of the matrix***

Meaning: poor correlation

The percentage of validated cells is abnormally low, appears when the correlation between the resistivity measurement of particles and their optical measurement is less than 50%.

Suspected abnormalities:
- Stroma interfering with measurement,
- Strong pollution,
- Incorrect adjustment of the optical bench.

***Others***

- From LMNE Matrix: **NO** flag
- From WBC Balance: **LMNE+**; **LMNE-**
- From WBC/BASO Histogram: **BASO+**

# 8. CLEANING

## 8.1. Automatic cleaning

• When the instrument has run 75 specimens from the date changing, an automatic cleaning procedure is carried out.

• The automatic cleaning frequency can be adjusted by the user from 1 to 75 as described in Chapter 4. Instrument configuration.

## 8.2. End of the day rinsing

• It is necessary to run a «**Shutdown**» cycle at the end of the day.
Press Shut Down button, the instrument performs a complete cleaning with *ABX* cleaner, and puts the system in stand by mode.

• The instrument can be switched off if the working day is completed or left in standby mode overnight or until the next analysis.

**NOTE**

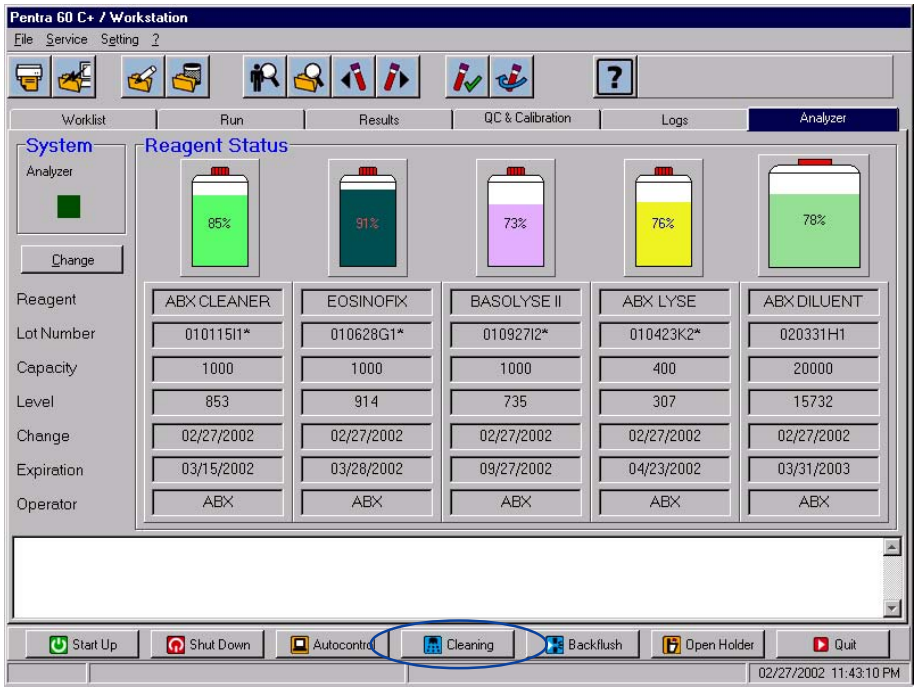
***A startup cycle is required systematically after a shutdown cycle if the instrument has to be operated.***

• After a Shutdown cycle a Startup cycle is required before running an analysis.
Click Start Up button before sampling otherwise the following message will be displayed:

## 8.3. After two or four hours of instrument inactivity

• If the instrument is not used for two hours a clean cycle will be necessary to run the next analysis. Click Cleaning button before sampling.

• If the instrument is not used for four hours a startup and a clean cycle will be necessary to run the next analysis. Click Start Up then Cleaning buttons before sampling.

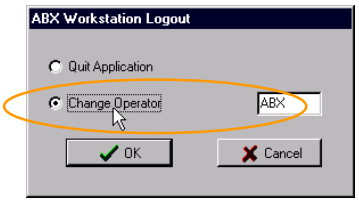

Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
System
Analyzer
Change
Reagent Status
85% 91% 73% 76% 78%
Reagent ABX CLEANER EOSINOFIX BASOLYSE II ABX LYSE ABX DILUENT
Lot Number 010115I1* 010628G1* 010927I2* 010423K2* 020331H1
Capacity 1000 1000 1000 400 20000
Level 853 914 735 307 15732
Change 02/27/2002 02/27/2002 02/27/2002 02/27/2002 02/27/2002
Expiration 03/15/2002 03/28/2002 09/27/2002 04/23/2002 03/31/2003
Operator ABX ABX ABX ABX ABX
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
02/27/2002 11:43:10 PM

# 9. CHANGE OPERATOR NAME

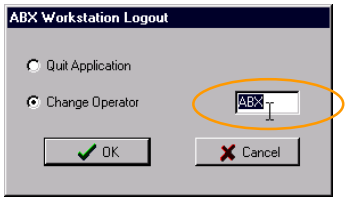
- To change the operator name, click button

.

- In the following window select «***Change Operator***» option:

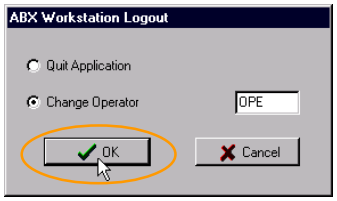



- Double click in the field «***Change Operator***» and enter the new operator name (3 letters max.):




- Click button

to validate modification:



# 10. WORKSTATION SHUT DOWN

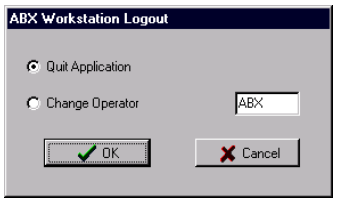
• At the end of the day press

button to perform a complete instrument cleaning with *ABX* cleaner.

• Click

button and confirm in the following window by clicking

button:




• Press ALT+CTRL+DEL (or ALT+CTRL+SUPPR) to open the «Logon window» and click «Shut down» button.

• The «Shutdown computer» window is opened, select «Shutdown» and click «OK».

• Wait until workstation shut down, then switch off the computer.

NOTE

***It is advise to shut down the computer from time to time to compact database.***

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# 1. CONTROL

• Quality control, for control bloods, allows for a set of analyses to be monitored based over a period of several months. Analyses are performed using known samples (also known as control blood or targets), the results are archived, and averaged, allowing statistical caculations to be extracted on the sample analysis system stability.
• For each control blood sample, up to 400 results can be archived in the database. 12 fields are reserved for Control blood lots and barcodes. To enter a new control blood you must modify one of these 12 fields.

## 1.1. New Clontrol blood lot setup

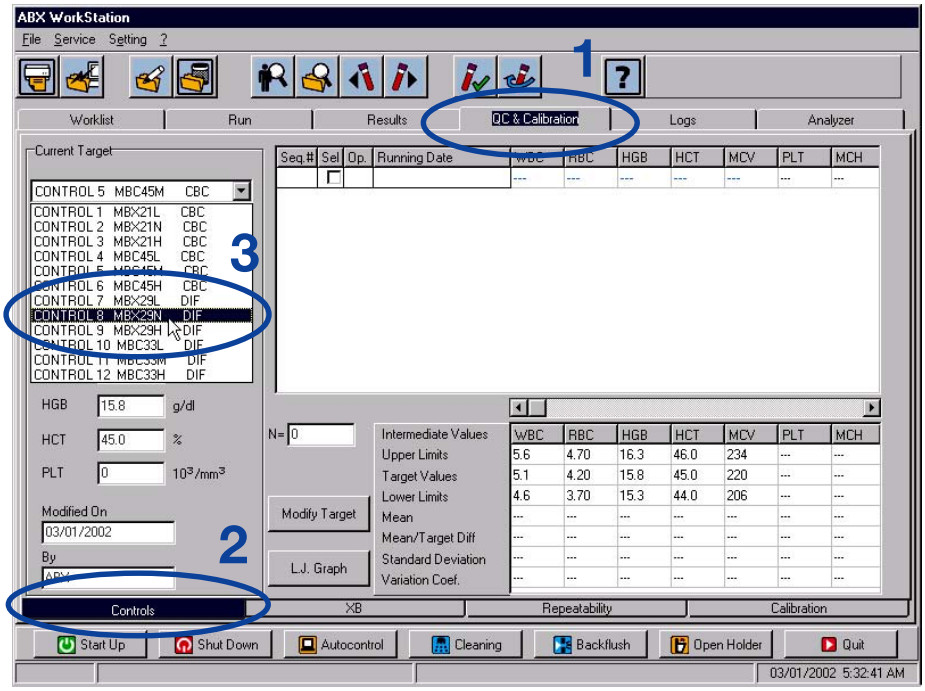
For example: New control blood lot parameters:
• Identification: JX99N
• Barcode: QC99N
• Expiration date: 07/19/2002

• *Select Contorl blood Lot you are going to modify (MBX29N for example):*

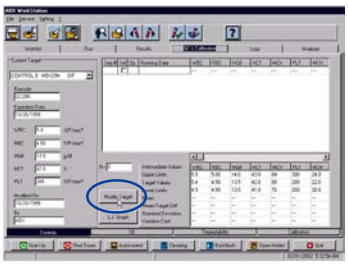
*1- Enter «**QC & Calibration**» Tab.*

*2- Enter «**Controls**» Tab.*

*3- Select control: Open «**Current target**» scrolling list and click on the control blood lot you want to modify.*

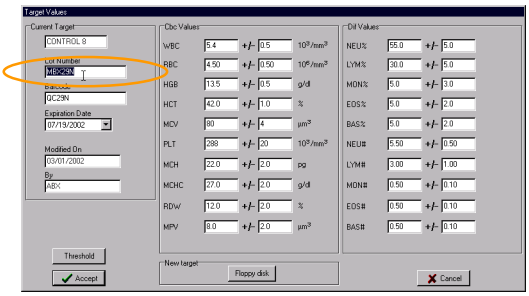



• Click on Modify Target button to open «**Target modify**» window:



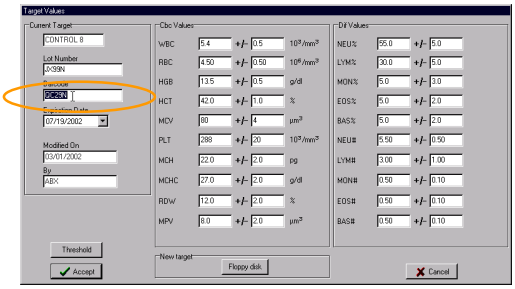
## ATTENTION

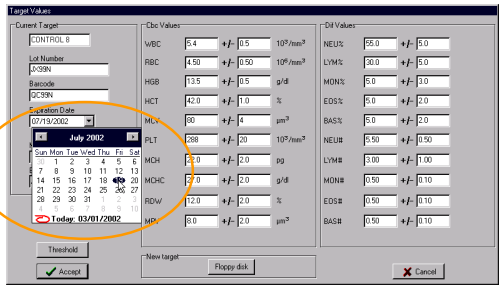
***If you replace or modify a control blood lot and you save modifications, all previous performed analysis with this lot will be lost.***



• Enter new control blood identification:
Click in «**Identification**» field in the «**Target modify**» window.
(For example: New control blood lot JX99N replaces MBX29N lot)

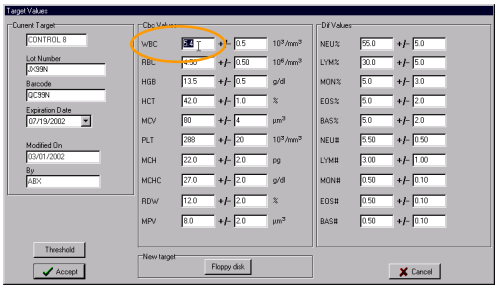
• Enter new calibrator Barcode:
Click in «**Barcode**» field in the «**Target modify**» window.
(For example: New barcode is QC99N and replaces QC29N)





• Enter new calibrator Expiration date:
Click in «**Expiration date**» field in the «**Target modify**» window. A calandar is opened, use LEFT and RIGHT arrows to scroll months, then years, and select the day with the pointer. (For example: new expiry date is the 07/19/2002)

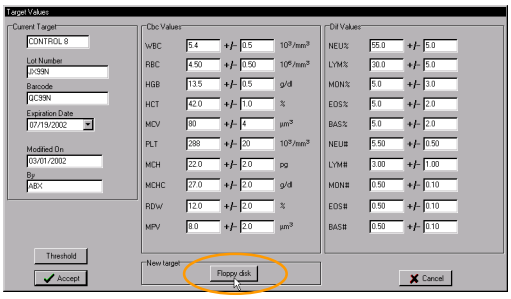
• Check that target values are correct, if they are not enter new target values, click over the figure you want to replace:



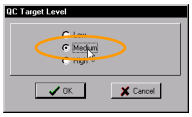
NOTE

***To update DIFFTROL control blood's alarm thresholds you must use the floppy disk.***

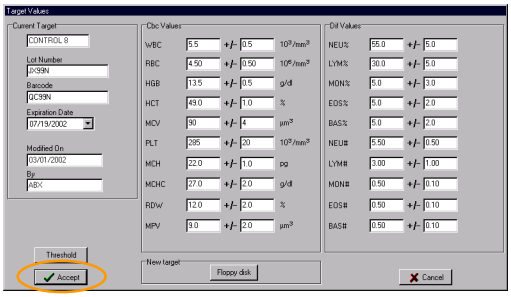
• You can use the floppy disk supplied by the Control blood lot to update automatically the target values, click button Floppy disk :



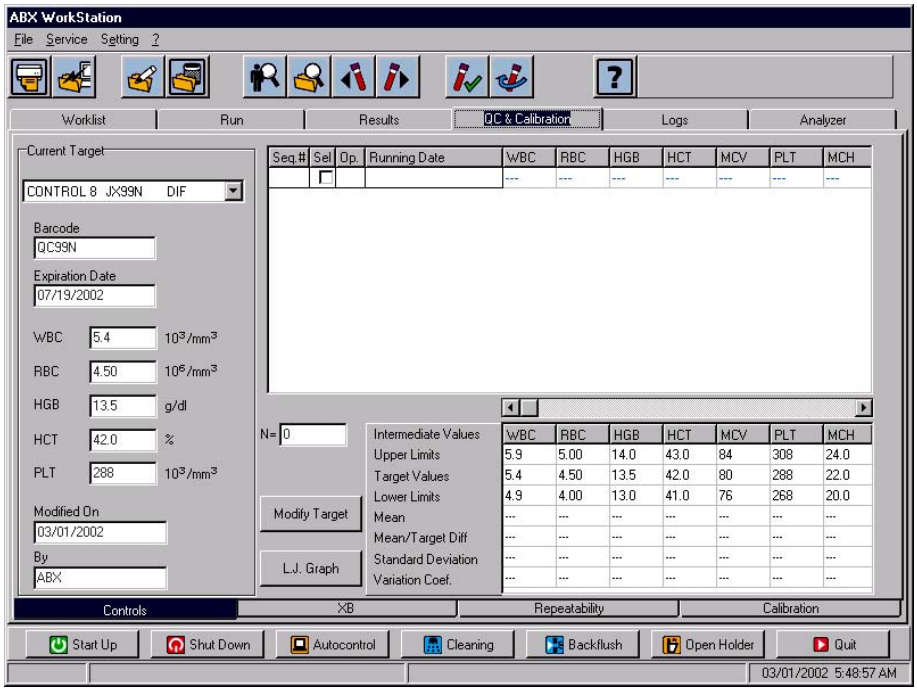
• Select the Control blood level (Low\Normal\High), then click OK



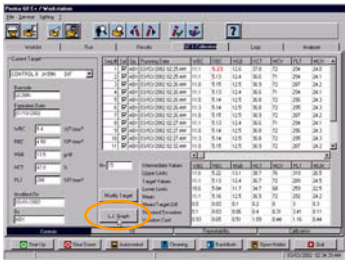
• Target values are updated, click button Accept to exit «**Target Values**» window and save modifications.



• «**QC & Calibration\Controls**» window is updated:

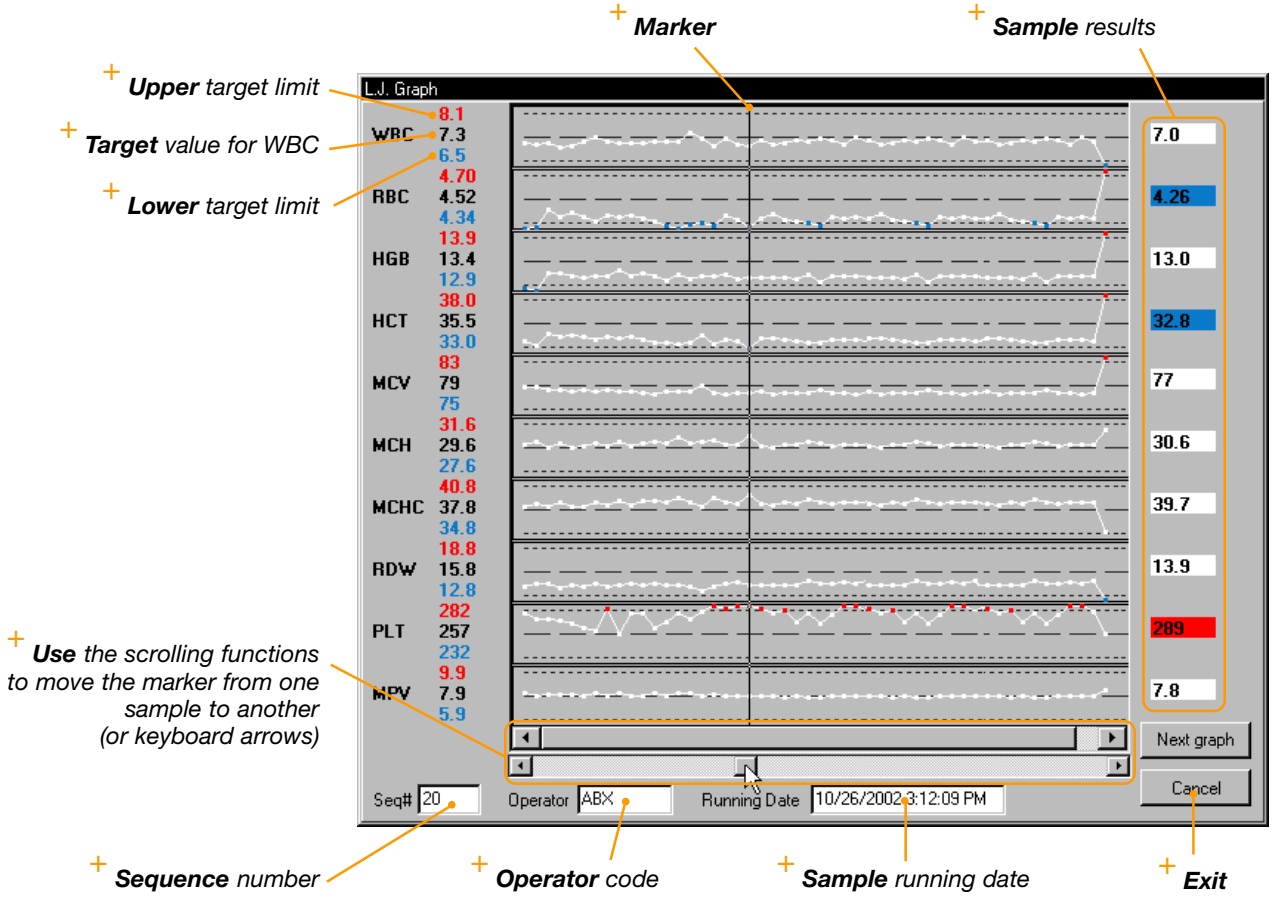


## 1.2. L.J.Graphs



• This is the graphical representation of the time evolution of each parameter in relation to the target value. Graphs are given for each control blood lot, include all the results (selected or not) and contain up to 400 results.

• A marker is used to point at any result of the graph in order to obtain the values. The points of a graph are displayed **white**, in **red** if the corresponding results are higher than the upper target limit and in **blue** if the corresponding results are less than the lower target limit.



# 2. CALIBRATION

• Calibration is a procedure to standardize the instrument by determining its deviation, if any, from calibration references and to apply any necessary correction factors.
• A minimum of three analyses cycles must be performed with a known sample (target) to calibrate the instrument. Results are averaged and new calibration coefficient values are calculated so as to generate results conforming to those supplied by the target.
• 6 fields (max. 11 results per fields) are reserved for Calibration blood lots and barcodes. To enter new parameters for a lot you must modify one of these 6 fields.

## 2.1. New Calibrator lot setup

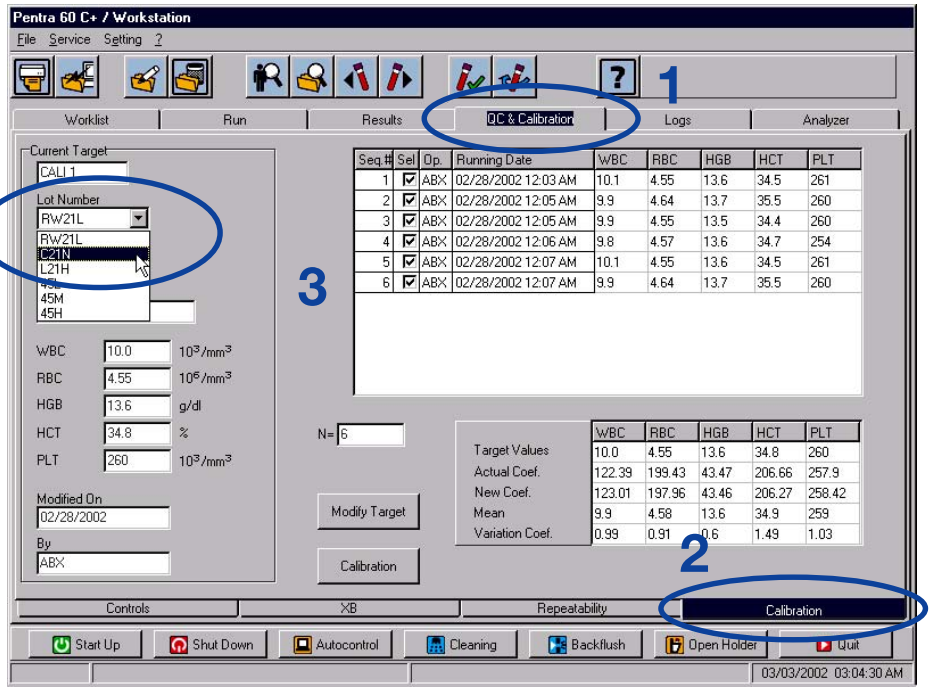
For example: New calibrator vial parameters:
• Identification: CX294
• Barcode: N412H
• Expiration date: 08/05/2002

• *Select Calibrator Lot number you are going to modify (C21N for example):*

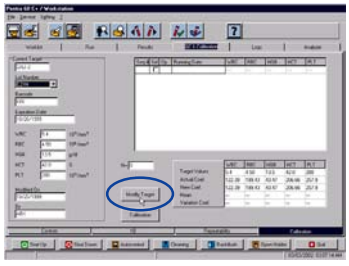
*1- Enter «**QC & Calibration**» Tab.*

*2- Enter «**Calibrators**» Tab.*

*3- Select calibrator: Open «**Ident**» scrolling list and click on the calibrator you are going to modify.*




• Click on Modify Target button to open «**Target modify**» window:

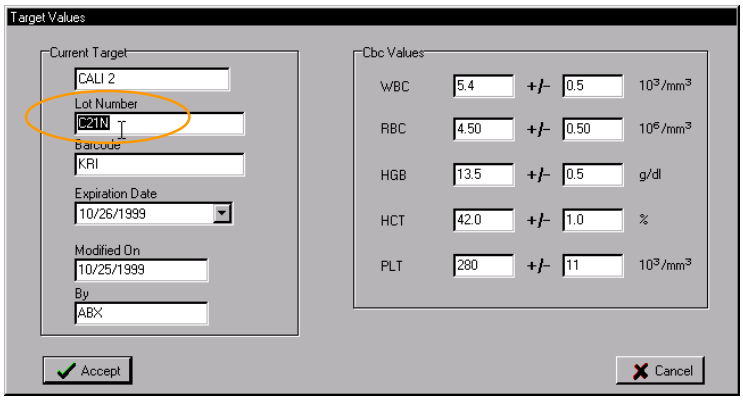


## ATTENTION

***If you replace or* modify a calibrator lot and you save modifications, all previous performed analysis with this lot will be lost.**

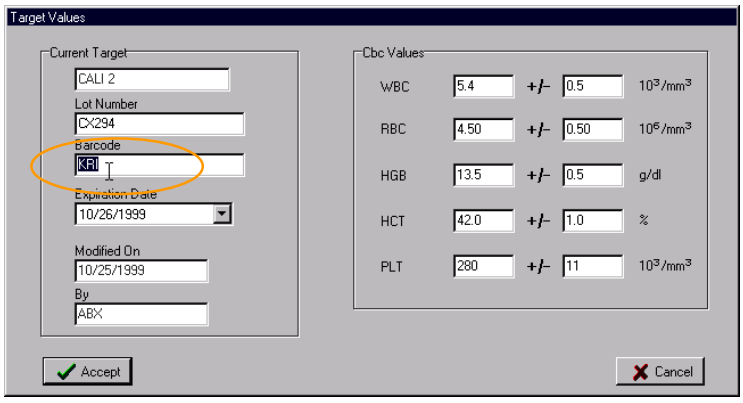
• Enter new calibrator identification: Click in «**Lot Number**» field in the «**Target Values**» window.

(For example: the calibrator C21N is replaced by CX294 calibrator)



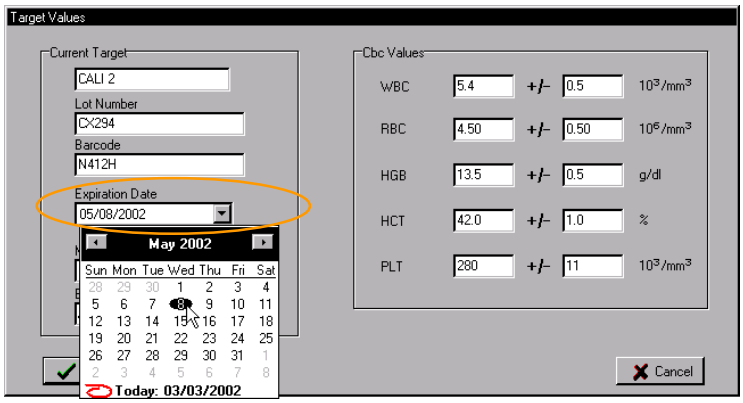

• Enter new calibrator Barcode: Click in «**Barcode**» field in the «**Target Values**» window.

(For example: the barcode KRI is replaced by N412H)

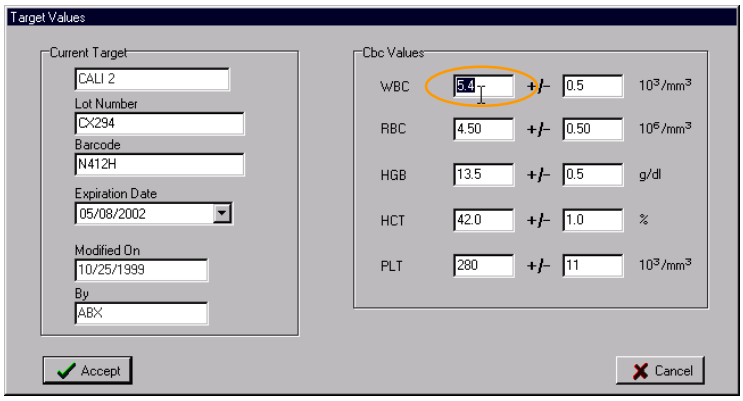



• Enter new calibrator Expiration date: Click in «**Expiration Date**» field in the «**Target Values**» window.

(For example: new expiry date is the 08/05/2002)

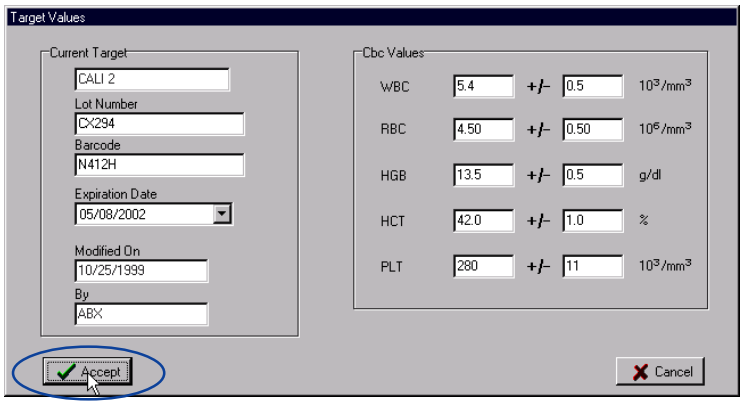


• Check that target values are correct, if they are not enter new target values, click over the figure you want to replace:

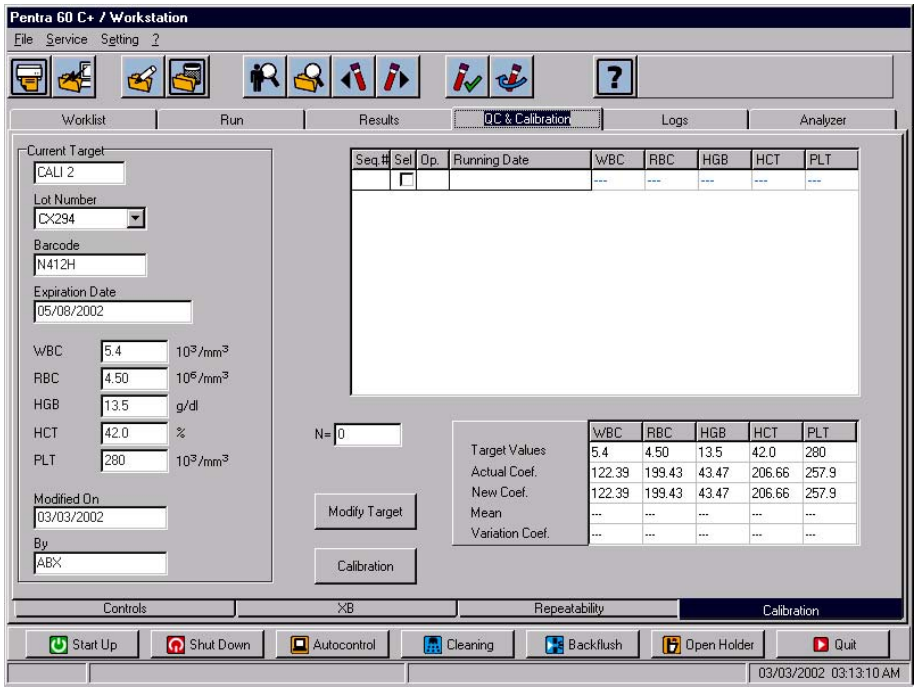



• Click on

button to save changes.



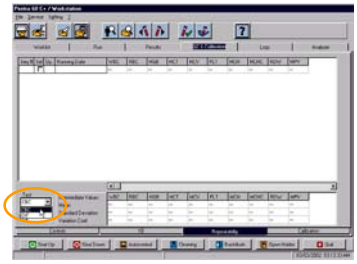

• «***QC & Calibration\Calibrators***» *window is updated:*



# 3. REPEATABILITY

• The measurement of repeatability is based on the set of results obtained from the consecutive analyses of the same human fresh normal blood sample.

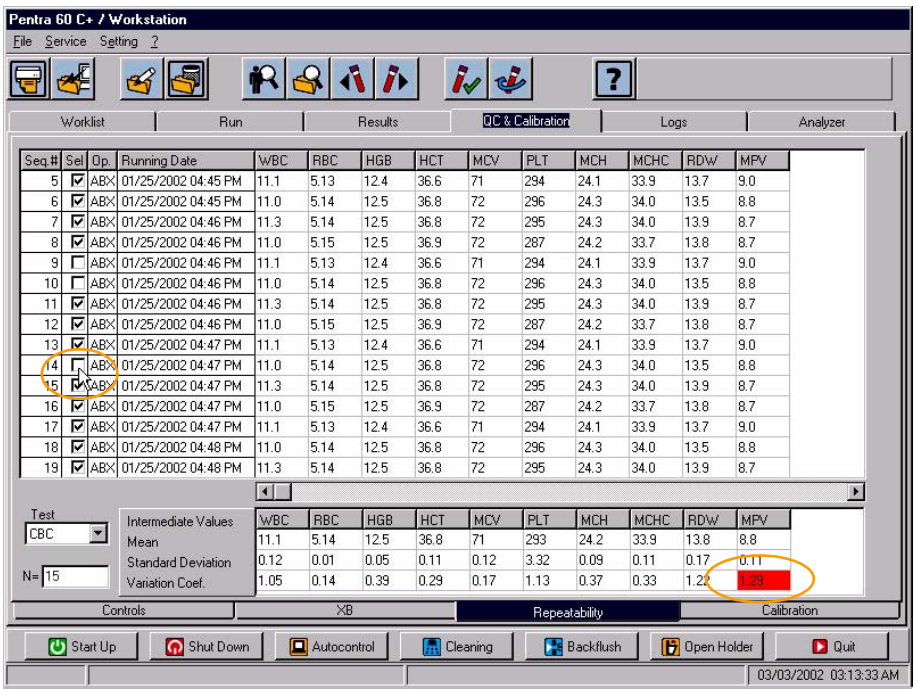
• CBC or DIFF type analyses can be invoked (combination is not supported) with a limit of 35 results per test. Beyond the 35th result, data generated from a new analysis will be disregarded.

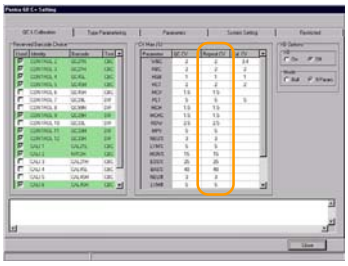


• To remain undisturbed the CV calculation, the potential results containing defaults generated directly from the analyses channels are rejected. In that case, a dialogue box informs the user:

• *Present the specimen as shown on the diagram below. When green LED is litten, close tube holder door to start sampling.*

• To perform a repeatability, run several samples in the «***Calibration&QC\Repeatability***» tab:

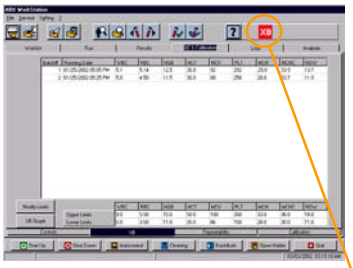


• Consecutive results are archived and statistical calculations are performed. Select, ☑, or unselect, ☐, results to use for CV calculation.

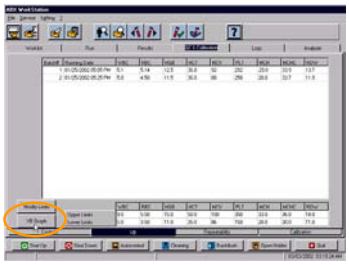
• If a CV in % is upper than the limit set by the user, it is displayed against a red background. CVs are adjustable by the «***System\QC & Cal.***» tab (see diagram beside).

# 4. PATIENT OR XB QUALITY CONTROL



• The «XB» function, Quality Control, is based on a BULL method and includes a calculation on 3 parameters or on 9 parameters (see configuration in *QC & Calibration* further in this chapter).This method allows the operator to follow the evolution of the system on a long-term basis and to check any factor which may eventually affect the quality of the results. Gradual alteration to the quality of the calibration blood or the quality of the reagents can thus be brought to the fore more easily.

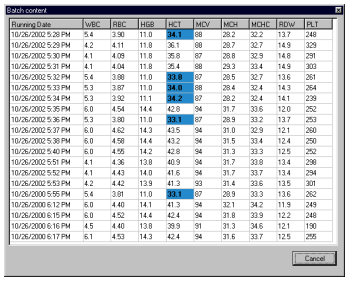
• The BULL calculation works automatically and progressively. It does not require any interventions from the operator, or the running of any specific controls. The statistical calculation includes all patient results that does not contain analysis default. When 20 results have been archived, a batch is calculated and archived also. A batch is a statistical point, each batch is included in the statistical calculation and gives a new point on the graph. Only the last 60 batches are archived, beyond 60 batches, the oldest batch will be overridden by the new one.



• A displayed alarm (XB) occurs if one parameter of this batch exceeds the XB limits, modifiable by the user (see configuration in *QC & Calibration* further in this chapter). This alarm is automatically deactivated following the inquiry of the XB tab.

• From the setting menu you can activate or deactivate the XB and the trigger of its alarm, or set the number of parameter from 3: MCV, MCG, MCHC to 9: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt.

• The statistical trend becomes more refined with time, according to the number of memorized samples.

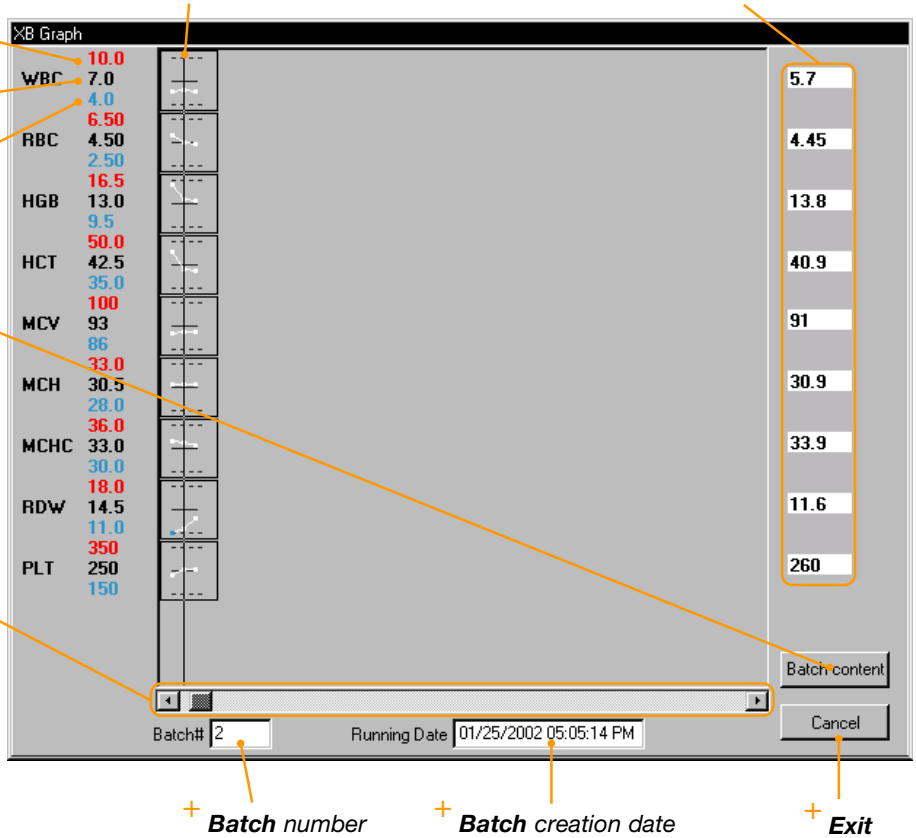


+ ***Upper** target limit*

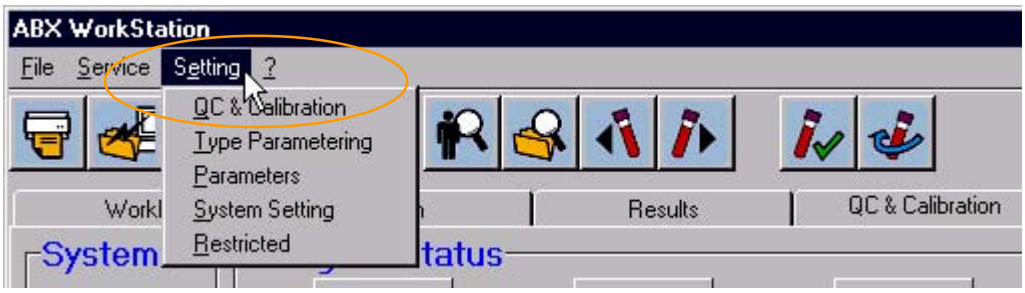
+ ***Target** value for WBC*

+ ***Lower** target limit*

+ ***Use** the scrolling functions to move the marker from one batch to another (or keyboard arrows)*



# 5. SETTING MENU




«***Setting***» menu, in menubar, allows user to setup:

- **QC & Calibration** options:
  - Control blood & Callibrator barcode choice,
  - Quality control & Calibration coefficients of variation,
  - XB alarm's options.

- **Type parametring** options:
  - Name,
  - Pathological levels,
  - Pathological limits,
  - Alarm levels,
  - Curves and matrix threshold,
  - Age range,
  - Setup default type.

- **System setting** options:
  - Date\Time format,
  - RS Communication,
  - Printer description,
  - Floppy format,
  - Cycle option,
  - Unit format, language selection,
  - Analyzer ID,
  - Barcode reader setup,
  - Save\Restore configuration.

- **Restricted** options (Password required):
  - Internal instrument parameters,
  - Calibration coefficients.

## 5.1. QC & Calibration

• Reserved Barcode Choice: Displays and allows selection of the barcodes associated to the QC targets: In event of selection (☑) , any attempt to use this barcode (in Worklist or as a priority entry) will invoke the switching of the result (treatment and archiving) in the corresponding section: QC or Callibration. In the event of non-selection (☐), the use of this barcode will have no effect on the passage of the cycle. The result is therefore switched to the routine environment.

• CV & Vario max (%): Adjustment of the QC, Repeatability and Calibration alarm limits. This box allows for the modification of the top CV limits or admissible variation expressed in % on the results of the Statistics & Calibration tab.

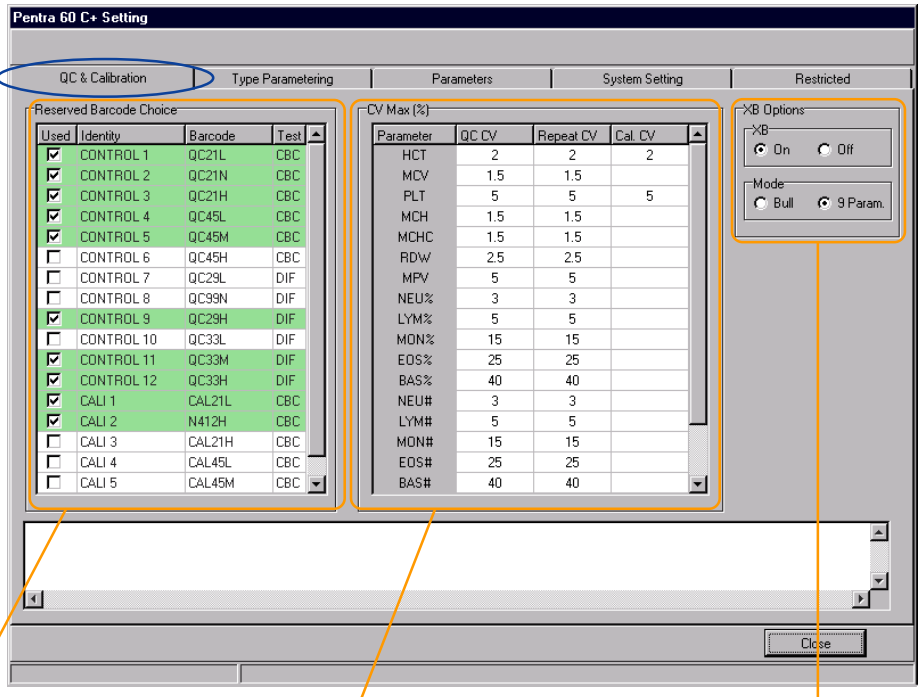
• XB Options: These options allow to setup the XB control number of parameters (3 or 9) and to set On/Off XB control system.

*• Double click into the field where you want to modify the value and enter new value.*

*• Once modifications are completed click on* Close *button to validate changes.*

**NOTE**

***Variation coefficients calculation for each parameter is done with unrounded values.***




+ ***Reserved*** *QC barcode selection.*

+ ***CV*** *adjustment for QC, Repeatability and Calibration.*

+ ***XB Options:***
***XB On/Off:***
*• Activates or deactivates XB function.*
***XB Mode:***
*• 3 parameters MCV, MCH and MCHC.*
*• 9 parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt.*

## 5.2. Type parametering

20 different blood types are available, 16 can be edited according to your own specifications, for each type you can setup:

- Type name,
- Type pathological limits & thresholds,
- Type alarm levels,
- Type alarms & curve thresholds.

*1- Enter «**Type parametering**» Tab.*

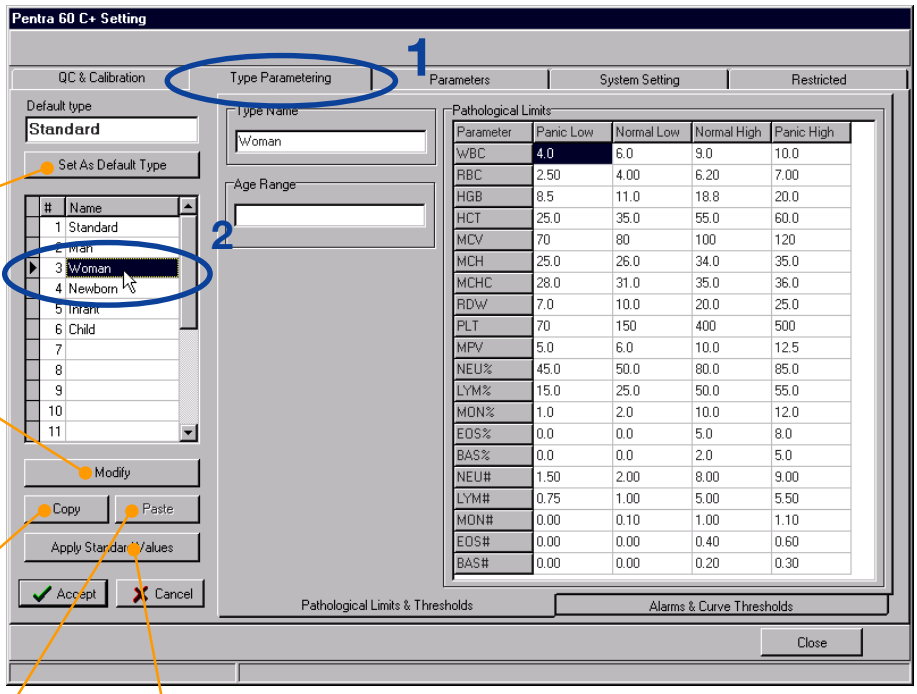
*2- Select the type to be displayed:*

+ ***Set as default type:** use this button to set type as default type when a new Patient file is created.*

+ ***Modifiy:** use this button to modify type setup.*

+ ***Copy:** use this button to copy all the values from the selected type.*

+ ***Paste:** use this button to paste all the previous copied values in the selected type.*

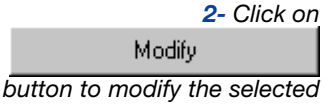



+ ***Apply standard values:** use this button to set type to default standard values.*

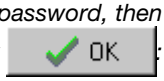
### 5.2.1. Type Name

*1- Select the type you want to modify the Name or create.*

*2- Click on*

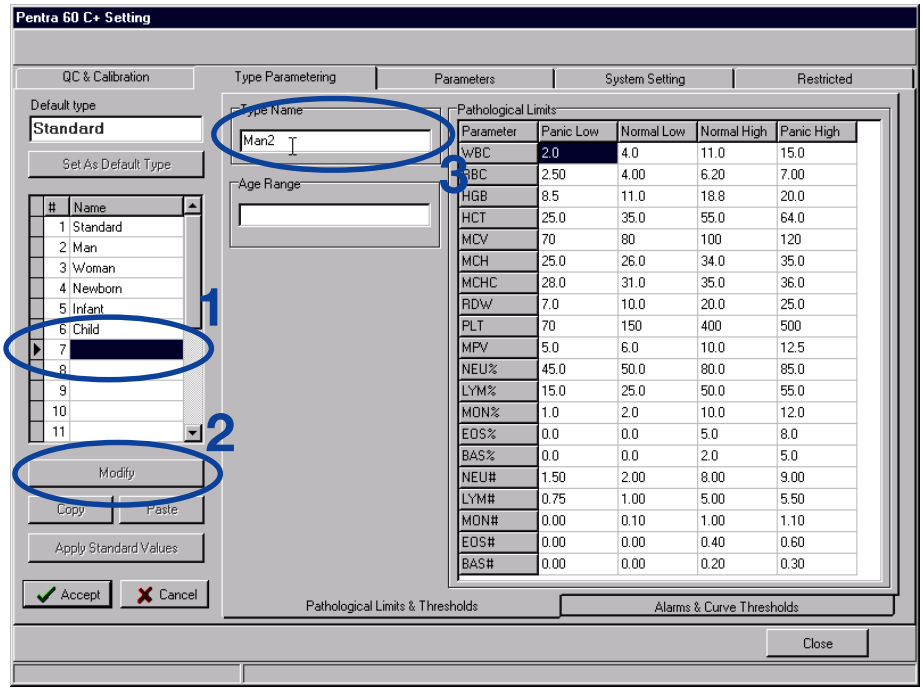



*button to modify the selected type.*

- *Enter «**User**» password, then click* 

:

*3- Click in the «**Type name**» field and enter new type name:*



## 5.2.2. Type Pathological Limits & Threshold

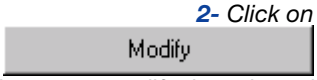
Laboratory levels can be set by the operator according to its own specifications:

Normal ranges:
Results that exceed the «**Normal ranges**» limits are identified with a flag:
- «**h**» for results above the upper limit,
- «**l**» for results below the lower limit.

Panic ranges:
Results that exceed the «**Panic ranges**» limits are identified with a flag:
- «**H**» for results above the upper limit,
- «**L**» for results below the lower limit.

*1- Select the type you want to modify the Pathological limits & thresholds.*

*2- Click on*



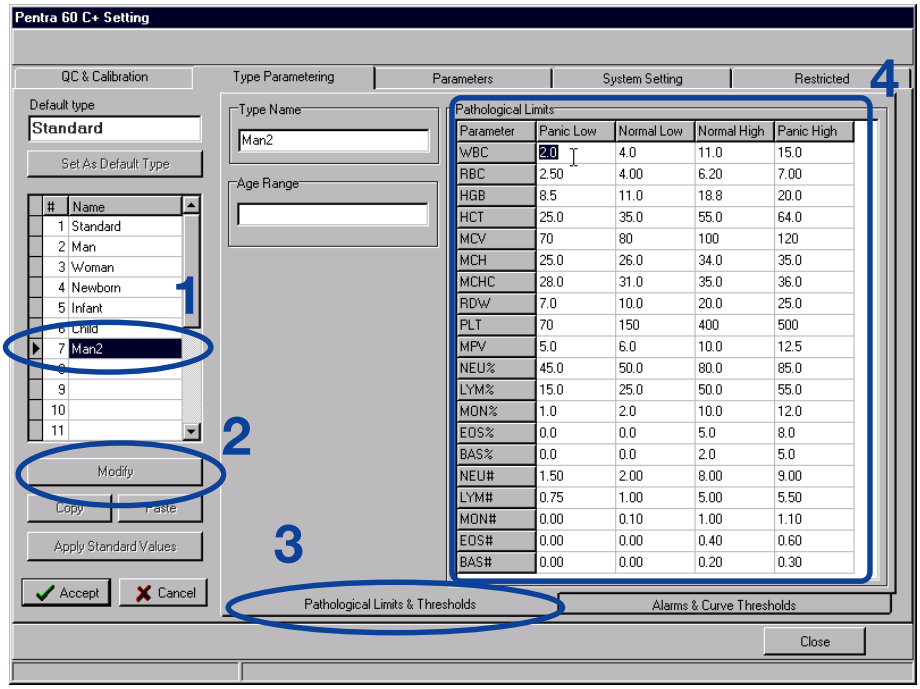

*button to modify the selected type.*

- *Enter «**User**» password, then click*

:

*3- Enter «**Pathological Limits & Thresholds**» tab.*

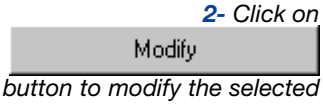
*4- Click in the field you want to modify the value and enter new value for this type:*



## 5.2.3. Type Alarm & Curve Thresholds

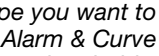
*1- Select the type you want to modify the Alarm & Curve thresholds.*

*2- Click on*

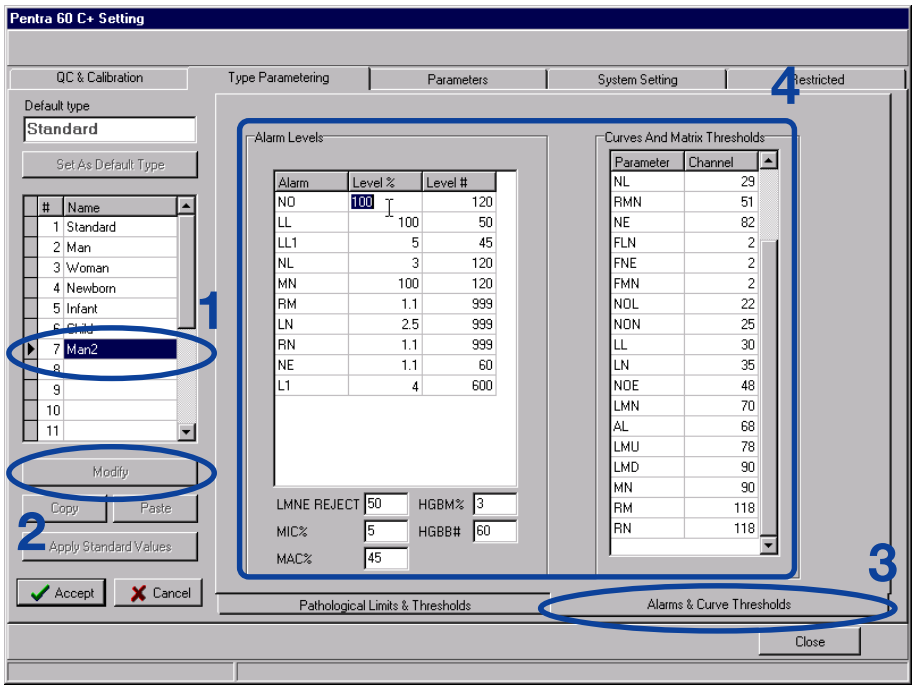



*button to modify the selected type.*

• *Enter «**User**» password, then click*




:




*3- Enter «**Alarms & Curve Thresholds**» tab.*

*4- Click in the field you want to modify the value and enter new value for this type.*

### *Alarms levels*

• Each flag is adjustable according to a percentage and (or) an absolute value. Beyond these values the corresponding flag is triggered off.

• The meaning of each flag is described in *Chapter 3. Specimen run & Results*.

• Note:
HGB% indicates the reject level between the three HGB measures.
HGB# allows to reject an HGB reference value that is faulty.

| Flag sensitivity standards | | | | | |
|---|---|---|---|---|---|
| Flags | % | # | Flags | % | # |
| LMNE REJ | 50 | 0 | RN | 1.1 | 999 |
| NO | 100 | 120 | NE | 1.1 | 60 |
| LL | 100 | 50 | L1 | 4 | 600 |
| LL1 | 5 | 45 | MIC | 5 | 0 |
| NL | 3 | 120 | MAC | 45 | 0 |
| MN | 100 | 120 | MACp | 11 | 0 |
| RM | 1.1 | 999 | HGB | 3.0 | 60 |
| LN | 2.5 | 999 | | | |

### *Curves and Matrix Thresholds*

• LMNE MATRIX THRESHOLDS

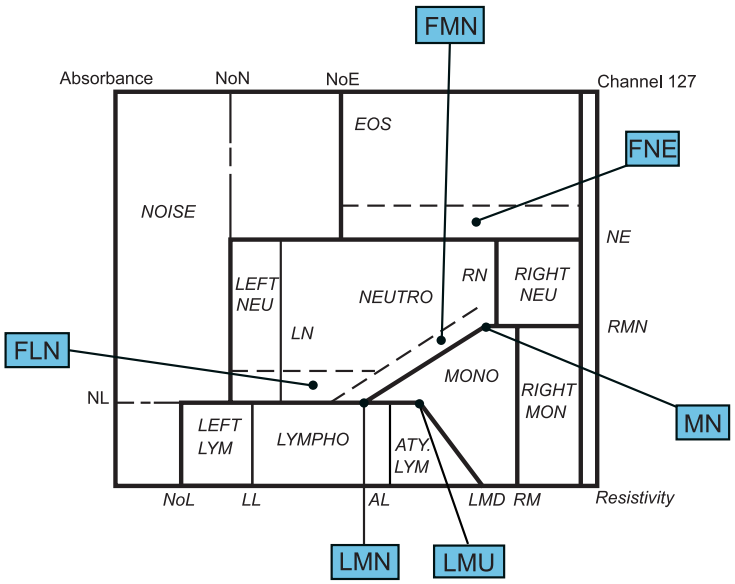
Each axis of the matrix (X and Y) is divided into 128 channels numbered from 0 to 127. 13 vertical indices (Y) and 13 horizontal indices (x) allow the user to locate these channels ten by ten. The first index of the matrix origin (at the bottom left) is the 0 channel, the fourth index of the matrix will be the channel 30 and so on. The threshold adjustment is expressed in channels.

+ ***Threshold*** *levels may be re-adjusted:*

• *To improve the separation between different cell populations which may vary according to the anti-coagulant in use or instrument internal adjustment.*

• *To modify the flag areas in one way or another to improve their detection sensitivity. In this case, the numeric adjustment of the concerned flag must also be readjusted (see* ***Alarm levels****).*

• *To modify one or several matrix areas in order to define more precisely a specific population for research purposes.*




• ***AC*** *thresholds (Absorbance) horizontally shown on the matrix:*

| Thres. | Purpose | Std. | Low limit | High limit |
|---|---|---|---|---|
| NL | Separation between Lymphocytes & Neutrophils | 29 | 0 | RMN |
| RMN | Separation between Right Mono & Right Neutrophils | 51 | NL | NE |
| NE | Separation between Neutrophils & Eosinophils | 82 | RMN | Channel 127 |

• *The **FLN**, **FNE**, **FMN** thresholds indicate the width (in channel number) of the **LN**, **NE**, **MN** alarm areas:*

| Thres. | Purpose | Standard |
|---|---|---|
| FLN | Channel number for the NL alarm area | 2 |
| FNE | Channel number for the NE alarm area | 2 |
| FMN | Channel number for the MN alarm area | 2 |

• ***DC** thresholds (resistive) vertically shown on the matrix:*

| Thres. | Purpose | Std. | Low limit | High limit |
|---|---|---|---|---|
| NOL | Separation between Noise and Left Lymphocytes | 22 | 0 | LL |
| NON | Separation between noise and Left Neutro | 25 | NoL | NoE |
| LL | Separation between Left Lymphocytes and Lymphocytes | 30 | NoL | AL |
| LN | Separation between Neutro and Left Neutro | 35 | NoN | LMN |
| NOE | Separation between Noise and Eosino | 48 | NoN | Channel 127 |
| LMN | Intersection dot between Lympho, Mono & Neutro thresholds | 70 | LN | LMU |
| AL | Separation between the Lympho and the Atypical Lympho | 68 | LL | LMU |
| LMU | Upper dot of the separation slope between Atypical lympho & Mono | 78 | AL | LMD |
| LMD | Lower dot of the separation slope between Atypical Lympho & Mono | 90 | LMU | RM |
| MN | Upper dot of the separation slope between Mono & Neutro | 90 | LMN | RM |
| RM | Separation between Monocytes and Right Monocytes | 118 | LMD | Channel 127 |
| RN | Separation between Neutro and Right Neutrophils | 118 | MN | Channel 127 |

• PLT CURVE THRESHOLD

The PL1 threshold is the number of the mobile channel that allows the calculation of the platelet population. It is automatically positionned.

+ ***See*** *PLT curve in* Chapter 3. Specimen run & Results.

| THRESHOLD | PURPOSE | STANDARD |
|---|---|---|
| PL1 | Do not modify (No effect) | Mobile |

• WBC CURVE THRESHOLDS

These thresholds are factory adjusted to the following values.

| THRESHOLD | PURPOSE | CHANNEL |
|---|---|---|
| *WBC*1 | Do not modify (No effect) | 4 |
| WBC2 | Do not modify (No effect) | 15 |
| WBC3 | Do not modify (No effect) | 240 |

• RBC CURVE THRESHOLDS

These thresholds are factory adjusted to the following values.

+ ***See*** *RBC curve in* Chapter 3. Specimen run & Results.

| THRESHOLD | PURPOSE | CHANNEL |
|---|---|---|
| RBC1 | Do not modify (No effect) | 54 |
| RBC2 | Do not modify (No effect) | 77 |

• BASO CURVE THRESHOLDS

All of the leukocytes are shown between the BA1 and BA3 thresholds.
L1 absolute value is calculated between the channel 0 and the BA1 threshold.
The percentage of basophils is calculated according to the number of particles from the BA2 threshold to the BA3 threshold.

These thresholds are factory adjusted to the following values.

+ ***See*** *BASO curve in* Chapter 3. Specimen run & Results.

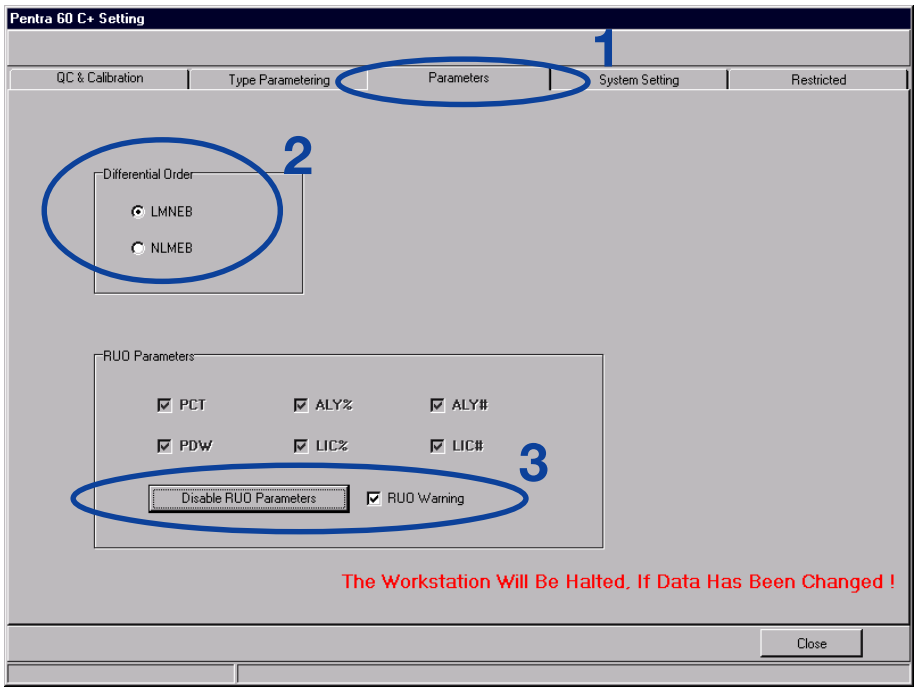
| THRESHOLD | PURPOSE | CHANNEL |
|---|---|---|
| BA1 | Separation threshold between the L1# counting area and the WBC | 35 |
| BA2 | Separation threshold between the WBC and basophils | 110 |
| BA3 | End of the basophil counting area | 240 |
| BA4 | Do not modify (No effect) | 255 |

## 5.3. Parameters

*1- Enter «**Setting\Parameters**» tab:*

*2- Select the differential presentation order:*

*3- Activate/Desactivate RUO parameters (Pct, PDW, ALY and LIC):*



## 5.4. System Setting

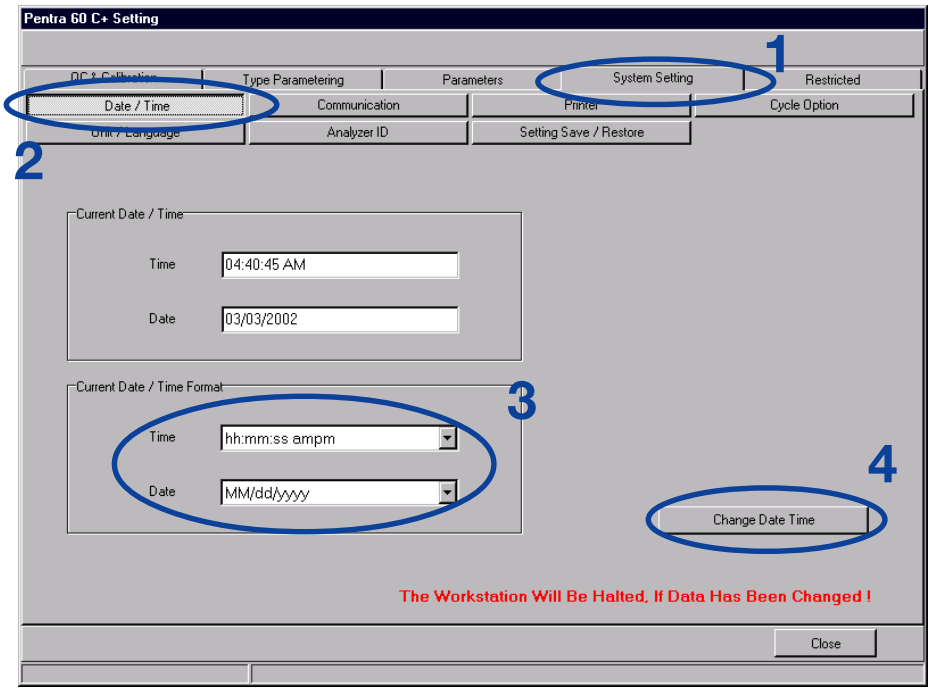
### 5.4.1. Date / Time

*1- Enter «**Setting\System Setting**» tab:*

*2- Select «**Date\Time**» option:*

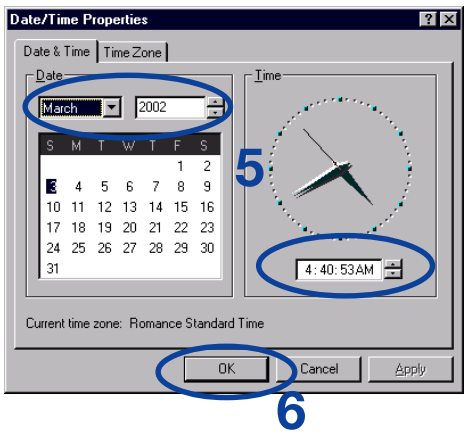
*3- Select Date \ Time display format with the scrolling boxes:*

*4- Press* Change date time *button:*




*5- Enter new Date/Time:*

*6- Click* OK *button to save changes:*

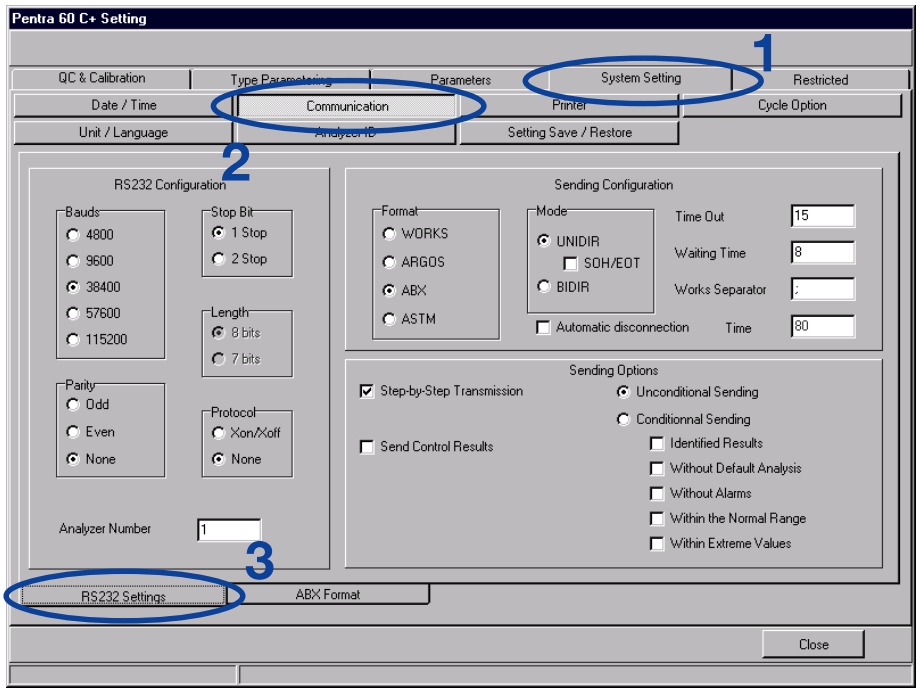


## 5.4.2. Communication

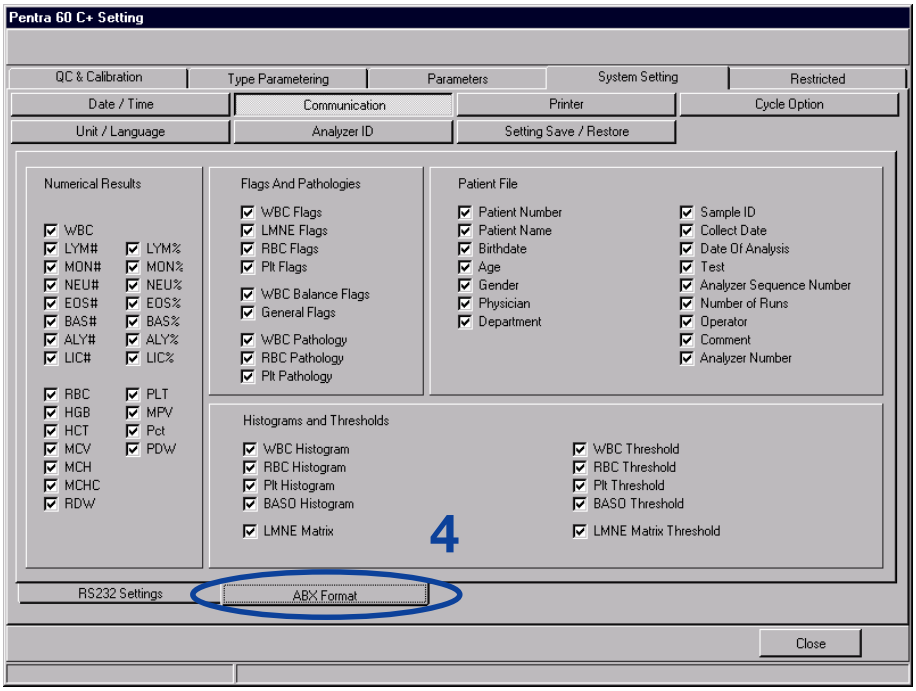
*1- Enter «**Setting\System Setting**» tab:*

*2- Select «**Communication**» option:*

*3- RS232 Setting.*

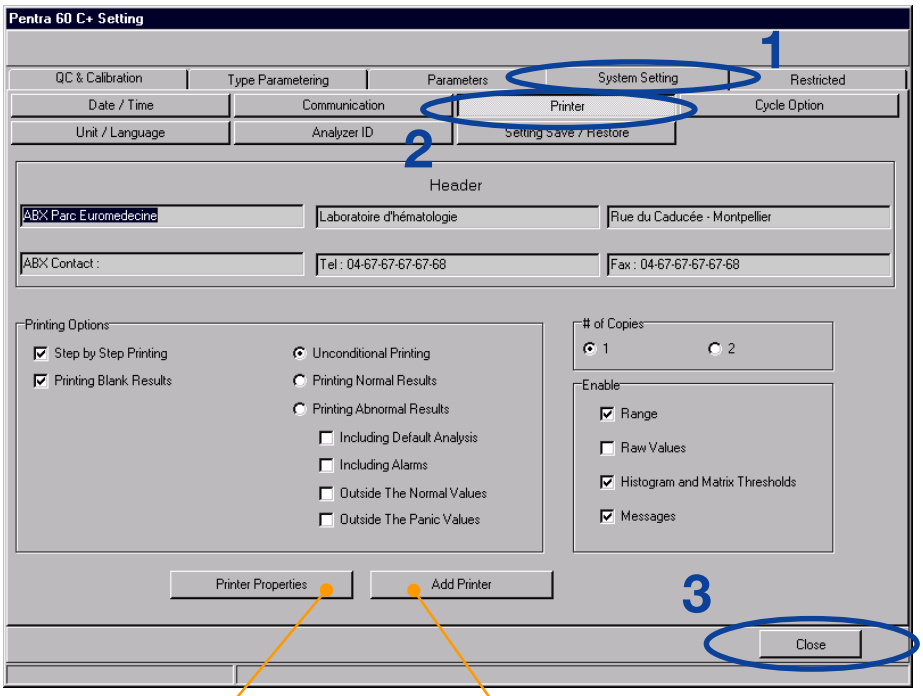



*4- ABX format.*



## 5.4.3. Printer

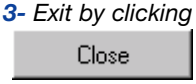
***1&2-*** *Enter «**Setting\System Setting**» tab and setup printer options:*




**NOTE**

***If window «Add Printer» or «Printer Properties» disappears, click another time on the button to make it appears again.***

***3-*** *Exit by clicking*




*button.*

+ ***Printer Properties:*** *Displays the printer properties window.*

+ ***Add Printer:*** *Open the dialog box to install new printer's driver.*

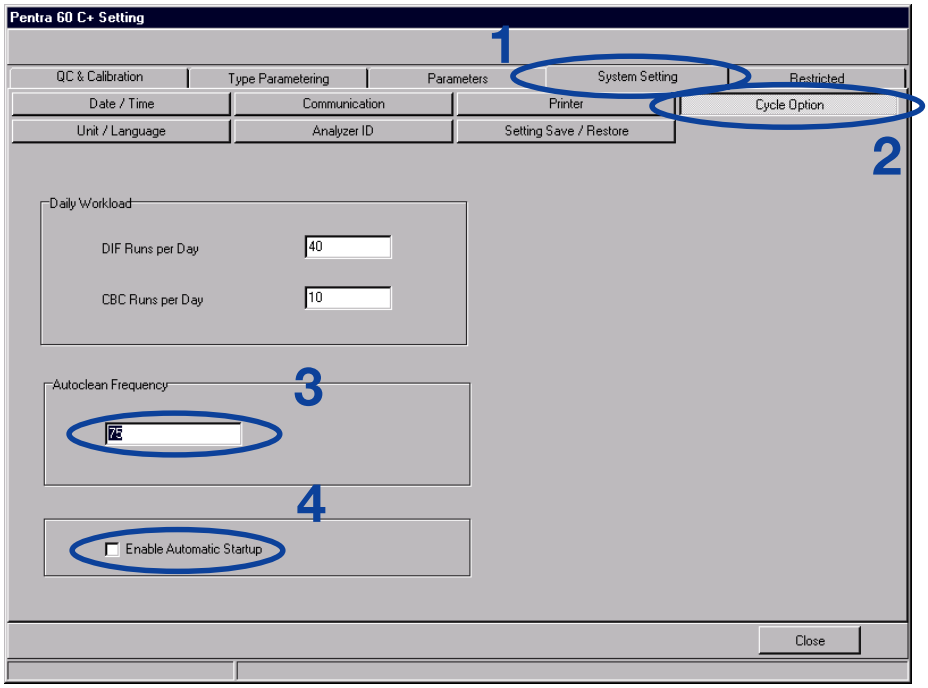
## 5.4.4. Cycle Option

*1- Enter «**Setting\System Setting**» tab:*

*2- Select «**Cycle Option**» option:*

*3- Enter Autoclean frequency (from 1 to 75):*

*4- Select «**Enable Automatic Startup**» option to run a startup cycle automatically when instrument is started:*



## 5.4.5. Unit / Language

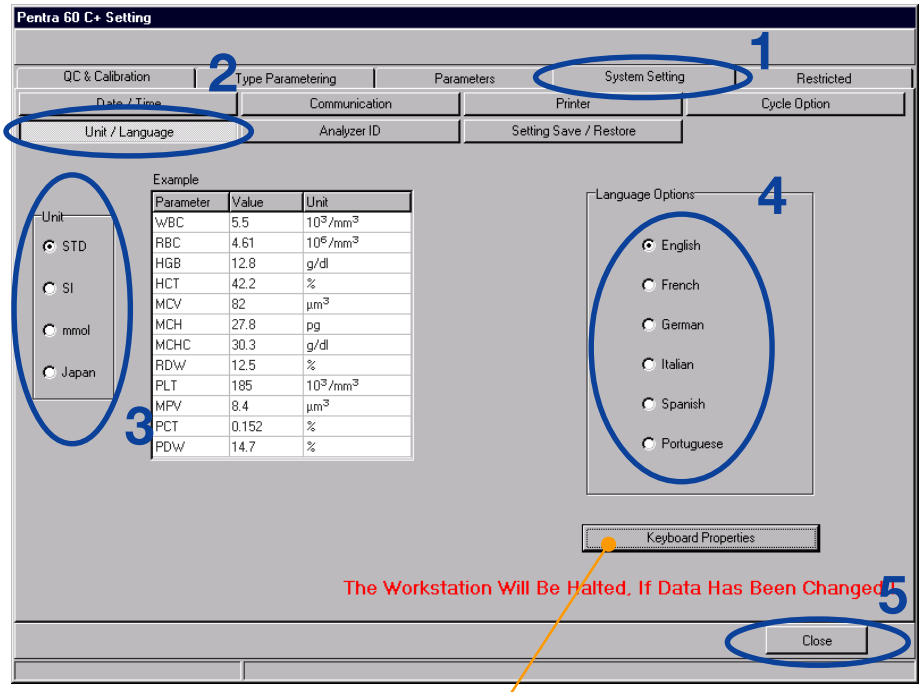
*1- Enter «**Setting\System Setting**» tab:*

*2- Select «**Unit / Language**» option:*

*3- Select the unit system you want to use:*

*4- Select the language option:*

*5- Exit by clicking* Close *button:*




+ ***Change input locales:*** *Allows to select different keyboard layouts. (Reserved for ABX Technician)*

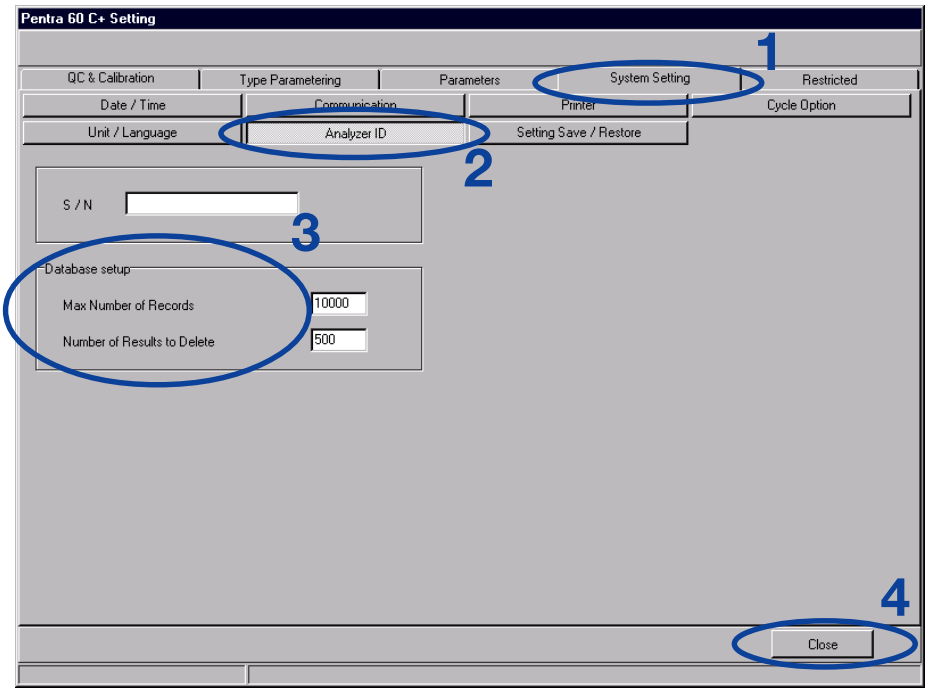
## 5.4.6. Analyzer ID

*1- Enter «**Setting\System Setting**» tab:*

*2- Select «**Analyzer ID**» option:*

*3- Database setup: «**Max Number of Records**» is the maximum number of records allowed to be stored in the database, before delation of a number of records set by «**Number of Results to Delete**»:*

*4- Exit by clicking* Close *button:*

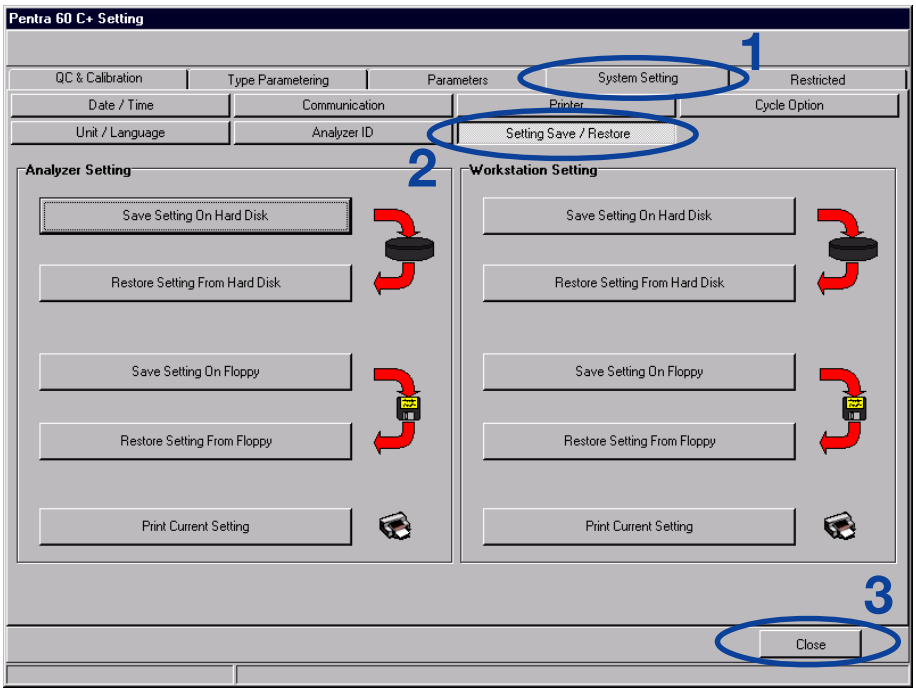


## 5.4.7. Config Save / Restore

*1- Enter «**Setting\System Setting**» tab:*

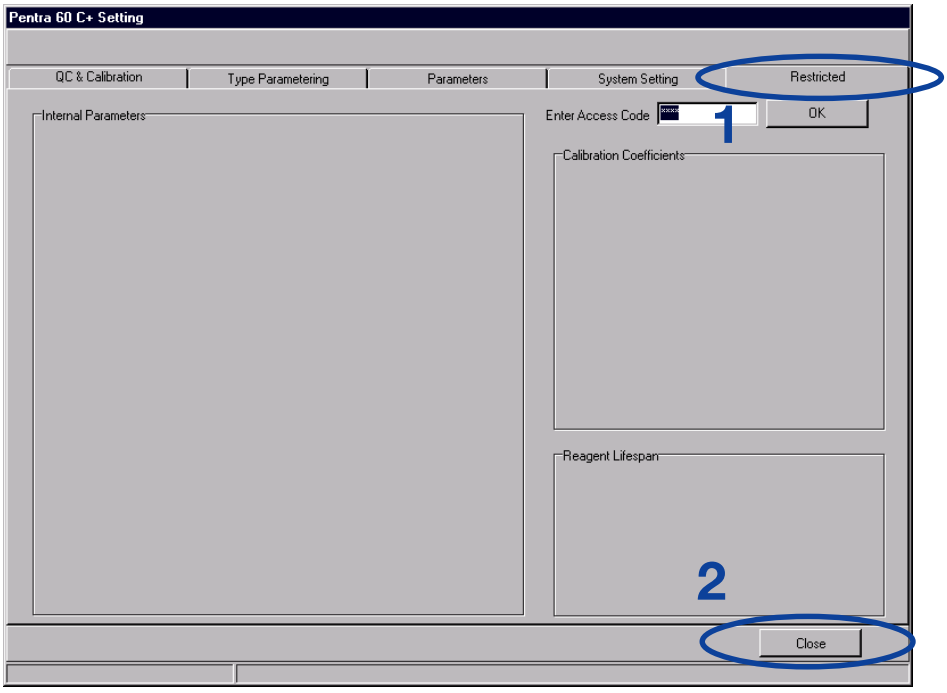
*2- Select «**Setting Save / Restore**» option and select the operation to be executed:*

*3- Exit by clicking* Close *button:*



## 5.5. Restricted (Reserved for Technicians)

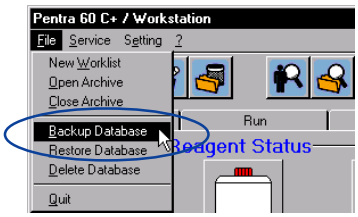
*1- Enter «**Setting\Restricted**» tab:*




*2- Exit by clicking* Close *button:*

# 6. BACKUP / RESTORE DATABASE

## 6.1. Backup database



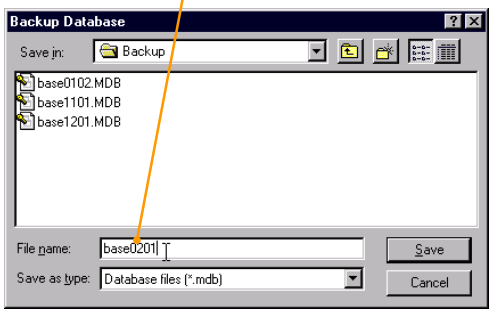

• Use command «**File\Backup Database**» to safeguard database: Current worklist as well as archived worklists, are compressed and stored on hard disk.

• It is recommended to safeguard database regularly to secure datas.

• From window «**Backup Database**» field «**File name**» enter the backup file name for the database (ex: «base0201»).

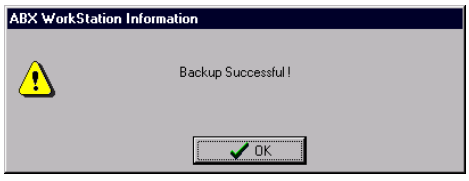
**ATTENTION**

***In order not to exceed hard drive capacity it is recommended to use same database backup file name for every backup (Previous backup with this file name will be lost). Call your ABX Diagnostics representative service department if hard drive capacity is exceeded.***




• Click button Save to start backup.

• When backup is finished the following window is displayed:

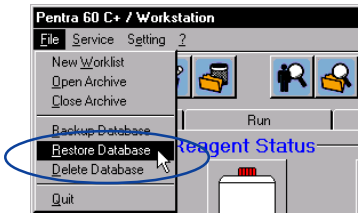



**ATTENTION**

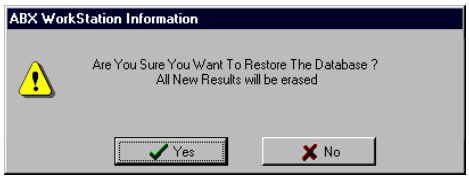
***Backup duration (from 1 to 30 minutes) depends on the database length. To get a quick saving a weekly backup is recommended.***

• Click button OK to exit.

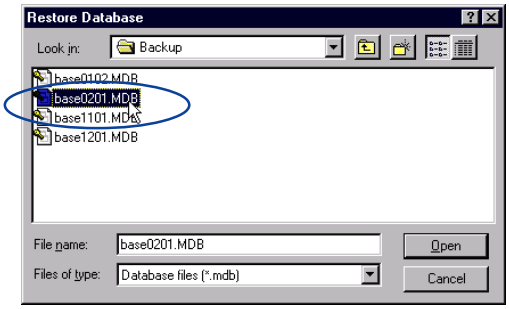
## 6.2. Restore database



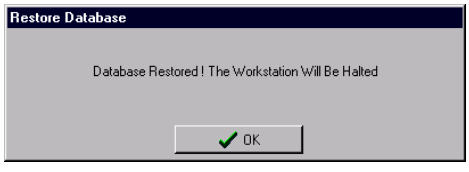

- Previous work, not saved since the last database backup and current worklist will be lost if a database is restored.
- Use command «***File\Restore Database***» to restore one of the database backup.
- The following window appears, confirm restoration by clicking Yes:



- Enter user password, then validate by clicking button OK.
- Select the backup to be restored:

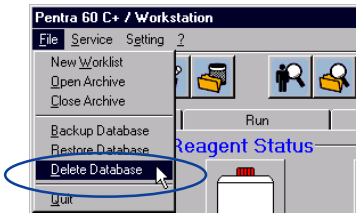



- When database restoration is ended the following message is displayed, click button OK to exit:




- Workstation is restarted.

## 6.3 Delete Database



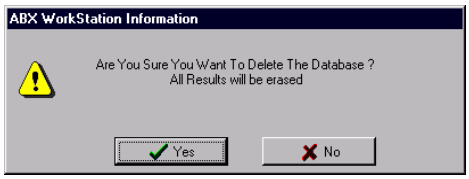

• «***File\Delete Database***» option erases all the results, and the worklist, from the current database.

• Enter user password, then validate by clicking button

.

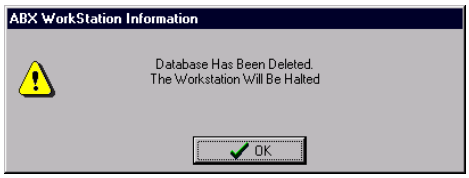
• Confirm delation by clicking button

:




• When delation is finished the following message is displayed, click button

to exit:




• Workstation is restarted.

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# 1. REPLACEMENT PROCEDURES

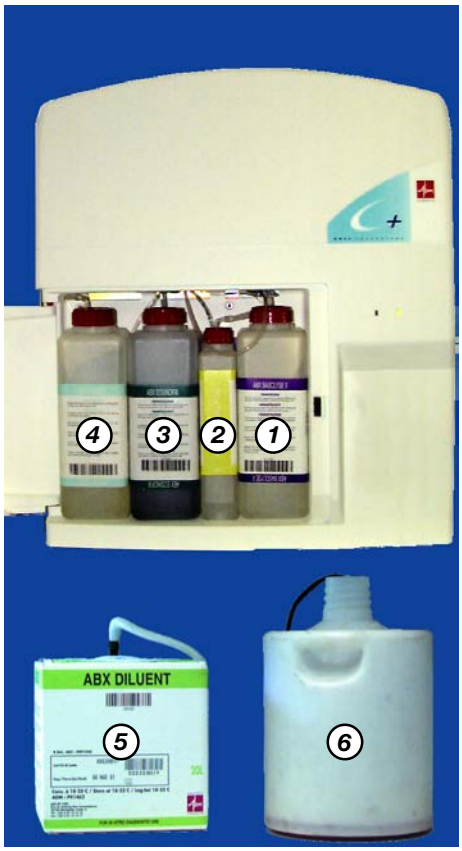
## 1.1. Reagent replacement

### 1.1.1. Reagent locations and connections

**IMPORTANT**

***Risk of erroneous results if diluent container is installed further than 80cm (31.5 in.) bellow the instrument.***

- ***Diluent input tubing: cristal 3x6 / 2 meters (80 in.) maximum.***
- ***Waste output tubing: cristal 4x6 / 2 meters (80 in.) maximum.***




***1- ABX Basolyse II***

***2- ABX Lyse***

***3- ABX Eosinofix***

***4- ABX Cleaner***

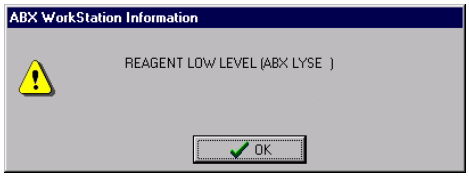
***5- ABX Diluent***

***6- Waste container***

## 1.1.2. Bottle replacement

• At instrument startup the remaining quantity of each reagent is compared to the daily workload setup by user. If a reagent Low level is expected during working day, the following box is displayed:

+ ***You*** *can click* OK *and continue tu run specimens until the message appears again, then concerned reagent must be changed.*




**IMPORTANT**

***Risk of erroneous results if one reagent is poured to another container. Never pour reagents from one container to another. Particles at the bottom of the old container can contaminate the new ragent and will cause uncceptable background results especially for Plts.***

• Open the reagent front door,

• Remove the specified bottle from the reagent compartment and unscrew the bottle stopper assembly.

**NOTE**

***Properly dispose of the empty reagent bottle.***

• Uncap a new reagent bottle,

• Insert the stopper assembly tube into the new bottle and tighten to ensure an adequate seal.

• Put the new reagent bottle in the reagent compartement and close the door, properly dispose of the empty bottle.

• Confirm reagent bottle replacement in software (as described further).

### 1.1.3. Diluent container replacement

**IMPORTANT**

***Make sure diluent container is no more than 80cm (31.5 in.) bellow the instrument.***

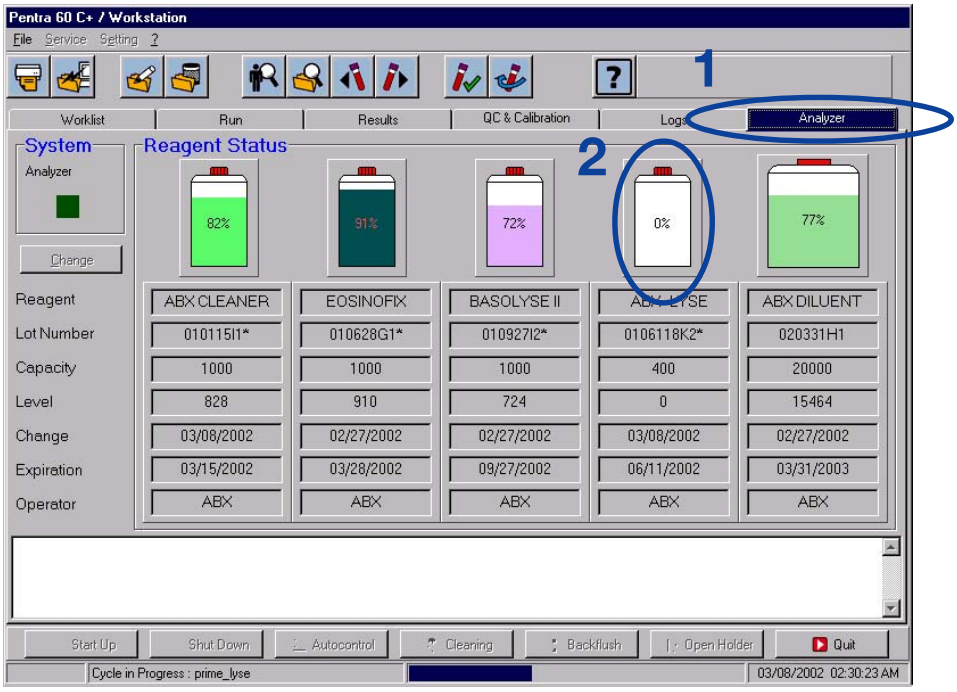
- Unscrew the diluent container stopper assembly,
- Uncap a new diluent container,
- Close the empty container with the cap,
- Insert the stopper assembly into the new diluent container and tighten it,
- Confirm diluent replacement in software (as described further).

### 1.1.4. After a Reagent replacement

- When a reagent is replaced you need to confirm and update the ***ABX WORKSTATION*** software.

*1- In «**Analyzer**» tab,*

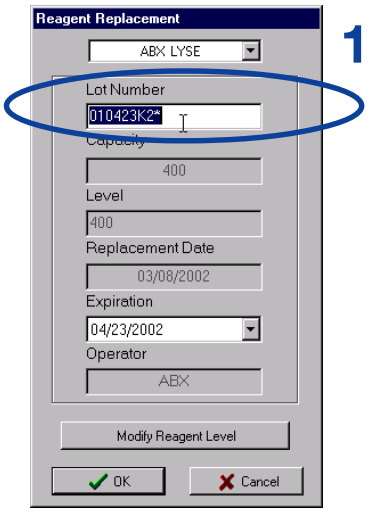
*2- Double-click on the reagent bottle icon you want to replace (for example **ABX Lyse**):*




**NOTE**

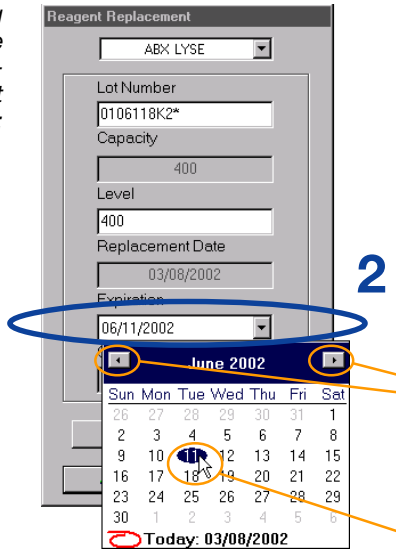
***You can either click*** Change ***button to open «Reagent replacement» dialog box.***

- *The «**Reagent replacement**» dialog box opens (**ABX Lyse** is selected in the reagent scrolling box):*




*1- Double-click in «**Lot number**» field, and enter new reagent lot number (this information is written on the reagent packaging):*

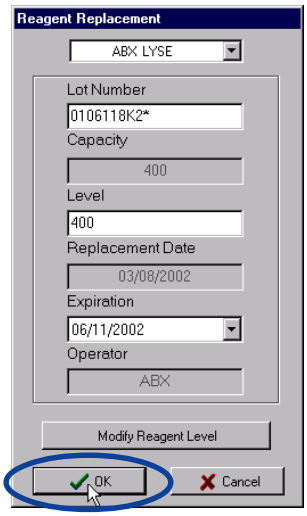
*2- Open «**Expiration**» scrolling list to select expiration date with a calendar (this information is written on the reagent packaging):*



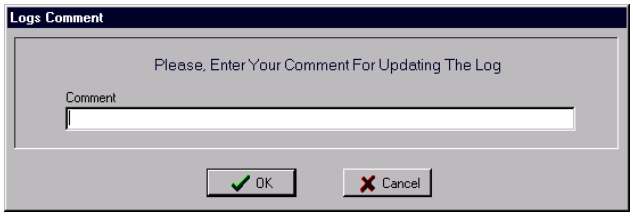

*Select Expiration date Month and Year with RIGHT and LEFT arrow buttons.*

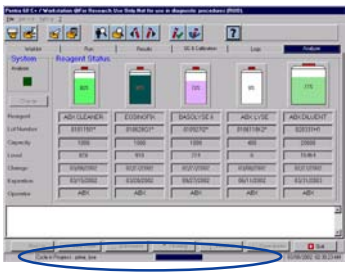
*Select Expiration date Day by clicking on the calendar (the calendar will be closed automatically).*

• *Click* OK *button to close window (or* Cancel *to exit without saving modifications),*



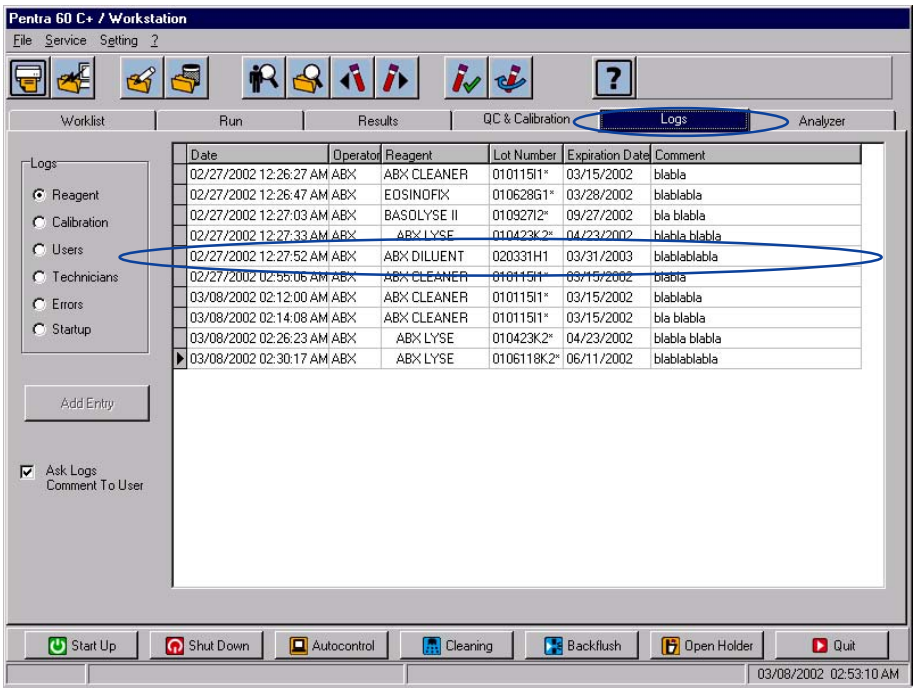

• *Enter comments about the reagent change (click* OK *or press ENTER to validate):*



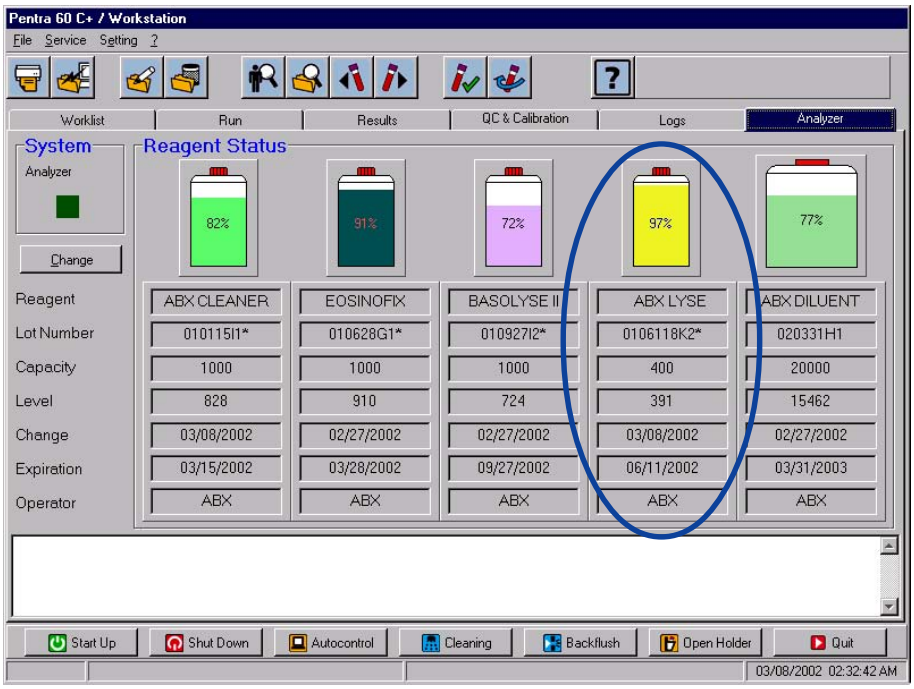



• A prime cycle is automatically started by the instrument.

• Change has been updated in the «**Logs**» tab:



• *Modifications are updated in «**Analyzer**» window:*



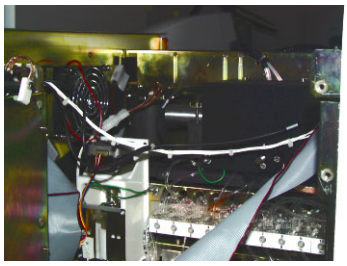

## 1.1.5. Waste container replacement

- Unscrew the waste container cap,
- Replace waste container according to your laboratory's protocol,
- Close the empty container with the cap and dispose of waste liquids according to your local/national organizations.

## 1.2. Optical bench lamp replacement

Lamp replacement (2 and 3mm hex keys required)

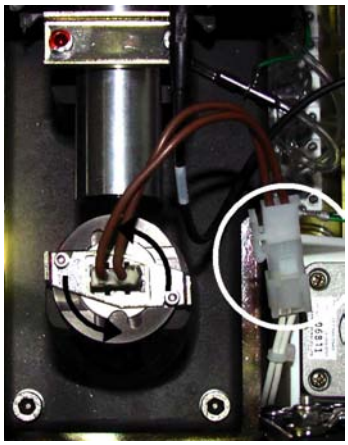
- Switch off the instrument and disconnect power supply cable,
- Remove the instrument cover:
  - Open the right door and unscrew cover screw in the upper front corner,
  - Unscrew the four screws of the left door,
  - In the left compartment unscrew the upper front corner screw,
  - Remove the six hex screws at the back of the instrument,
  - Remove instrument top cover carefully.
- Open mother board door (To keep the door open anchor it behind plastic catch).



**CAUTION**

***Becareful when you open motherboard door not to disconnect or damage flat cable connected behind it.***

- On the left top of the instrument locate the optical bench and the lamp (left side of the optical becnh).



**WARNING**

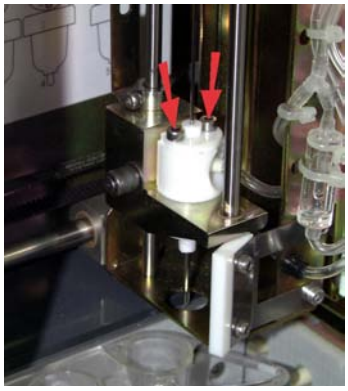
***Wait for the lamp to cool down before handling it.***

- Disconnect the lamp supply,
- Unscrew lamp fixation screws (few turns),
- Turn the lamp and remove it,
- Replace the lamp by a new one,
- Put back the fixation system and block the screws,
- Reconnect the lamp supply,

- Check that instrument operates normally:
  - Close the right door,
  - Connect power supply and start the instrument,
  - Check Lamp is lighted,
  - If it is wait until startup end, switch off the instrument and disconnect power supply cable, replace cover and close all doors, connect supply cable and turn the instrument on.
  - If not troubleshoot system to determine the problem.

## 1.3. Sampling probe replacement

- Switch off the instrument and disconnect power supply cable,
- Open the pneumatic access door (on the right side of the instrument),



- Untight both rinsing block screws,

- Lift locker to free the probe,

- Disconnect gently the tube from the probe and replace the probe.
- Re-assemble in reverse order, tight the rinsing block screws.
- When start up is done check for no leak.

# 2. MAINTENANCE

## 2.1. Hydraulic cycle maintenance chart table

• One of the principle factors contributing to accurate and reliable results is a well-maintained instrument. Several maintenance functions are available for the user to clean and check the instrument.

+ ***Frequency*** *of maintenance cycles depends on the laboratory sample output, perform maintenance according to the chart table beside:*

| MAINTENANCE CYCLES (ANALYSES/DAY) | LABORATORY OUTPUT ≤100 | LABORATORY OUTPUT >100 |
|---|---|---|
| Shut Down | 1 per day | 1 per day |
| *Autoconcentrated Cleaning* | *1 per month* | *2 per month* |

### 2.1.1. Shut down cycle

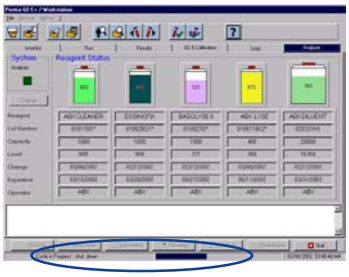
• At the end of each day do a Shut Down cycle to rinse the instrument (Fluidic tubing and apertures are cleaned to prevent instrument pollution).

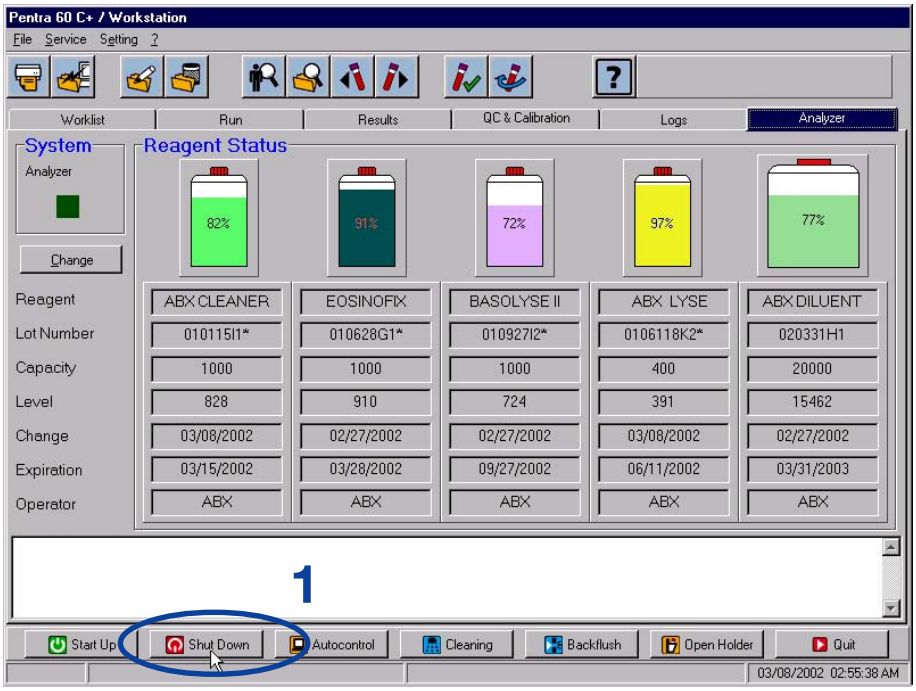
***1-*** *To run a Shut Down cycle* Shut Down *button:*

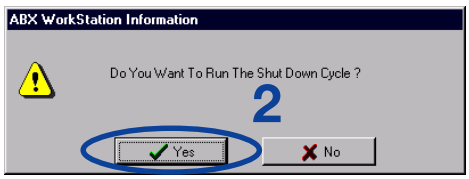
***2-*** *Confirm Shut Down cycle:*

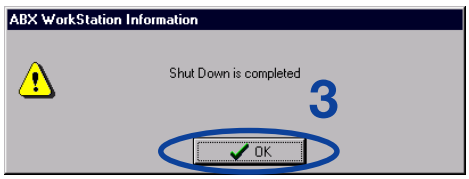
***3-*** *Click button* OK *when cycle is finished:*

+ ***During*** *cycle a progression a status bar is displayed:*




Pentra 60 C+ / Workstation
File Service Setting ?
Worklist Run Results QC & Calibration Logs Analyzer
System
Analyzer
Change
Reagent Status
82% 91% 72% 97% 77%
Reagent ABX CLEANER EOSINOFIX BASOLYSE II ABX LYSE ABX DILUENT
Lot Number 010115I1* 010628G1* 010927I2* 0106118K2* 020331H1
Capacity 1000 1000 1000 400 20000
Level 828 910 724 391 15462
Change 03/08/2002 02/27/2002 02/27/2002 03/08/2002 02/27/2002
Expiration 03/15/2002 03/28/2002 09/27/2002 06/11/2002 03/31/2003
Operator ABX ABX ABX ABX ABX
1
Start Up Shut Down Autocontrol Cleaning Backflush Open Holder Quit
03/08/2002 02:55:38 AM

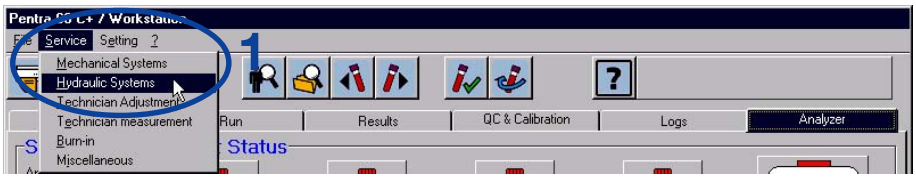


## 2.1.2. Concentrated cleaning

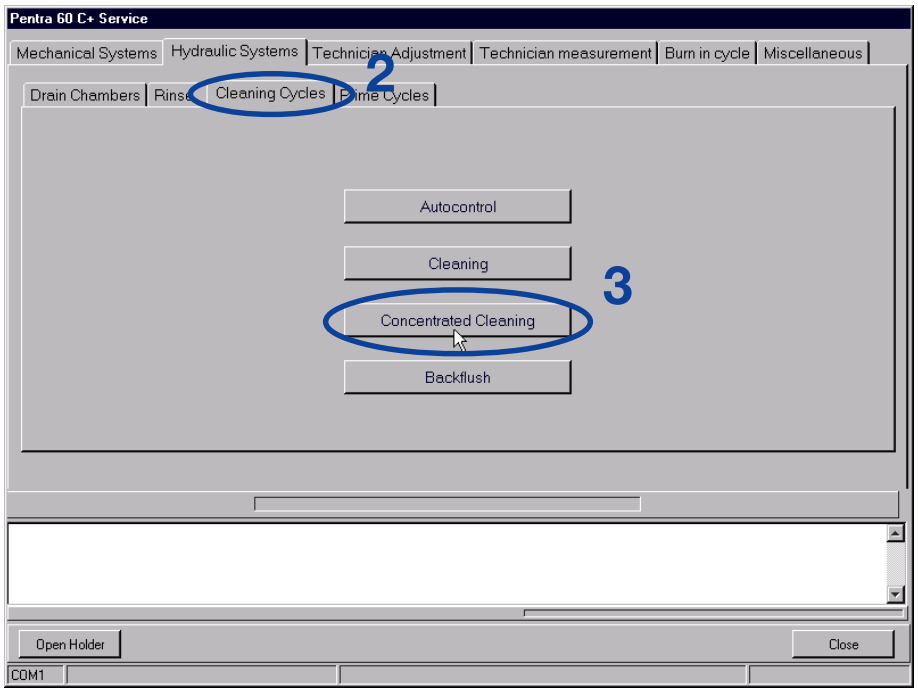
• Autconcentrated cleaning allows the chambers to be cleaned with bleach:

*1- Open «**Menu\Service\Hydraulic systems**» window:*

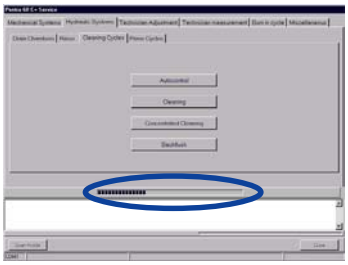



*2- Open «**Cleaning cycles**» tab:*

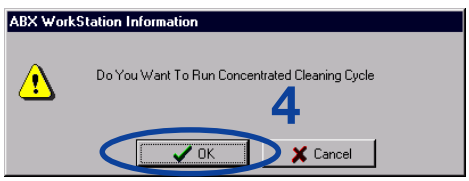
*3- Click* Concentrated cleaning *button:*



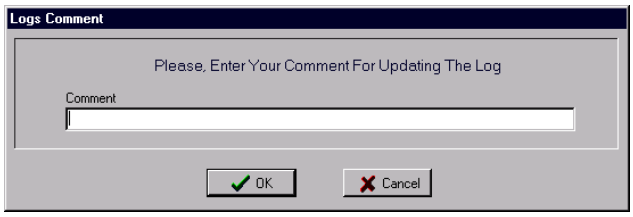

+ ***During** cycle a progression a status bar is displayed:*



*4- Confirm start of concentrated cleaning by clicking button* OK *:*

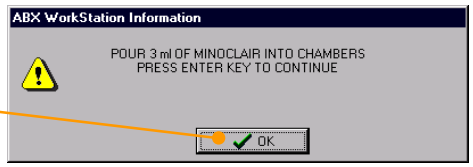


• *A rinse cycle is started. Enter the comments to update «**Reagent**» log:Wait until the instrument displays the following message:*

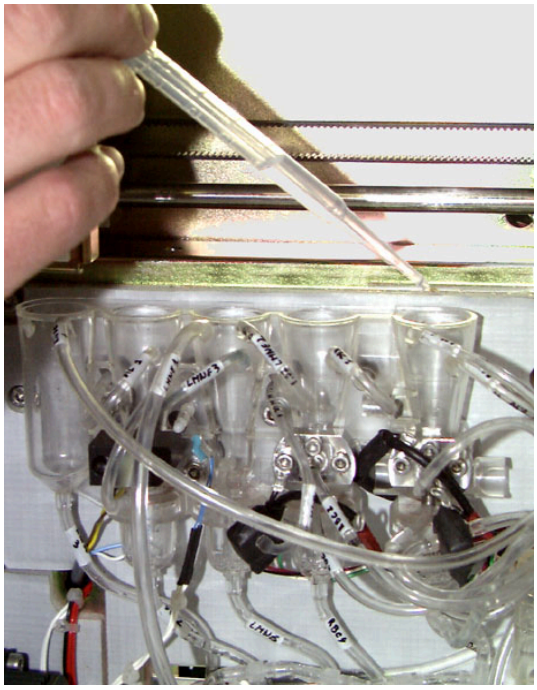



NOTE

***Do not click «OK» before you pour minoclair.***



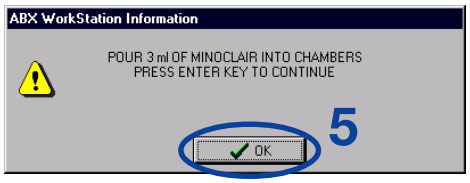

• *Open the instrument pneumatic door.*



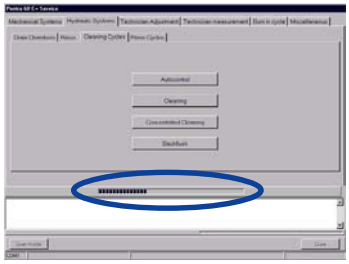
• *Use a 5ml syringe to pour 3ml of MINOCLAIR (or bleach diluted to 4° chloride) into each chamber and validate.*

• *Close the instrument door and wait for the instrument to complete the cleaning procedure (Concentrated cleaning duration is around 5 min.).*

***5-** Exit Concentrated cleaning cycle by clicking button* OK :

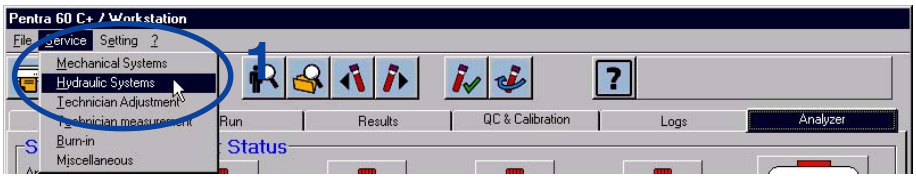



+ ***During** cycle a progression a status bar is displayed:*



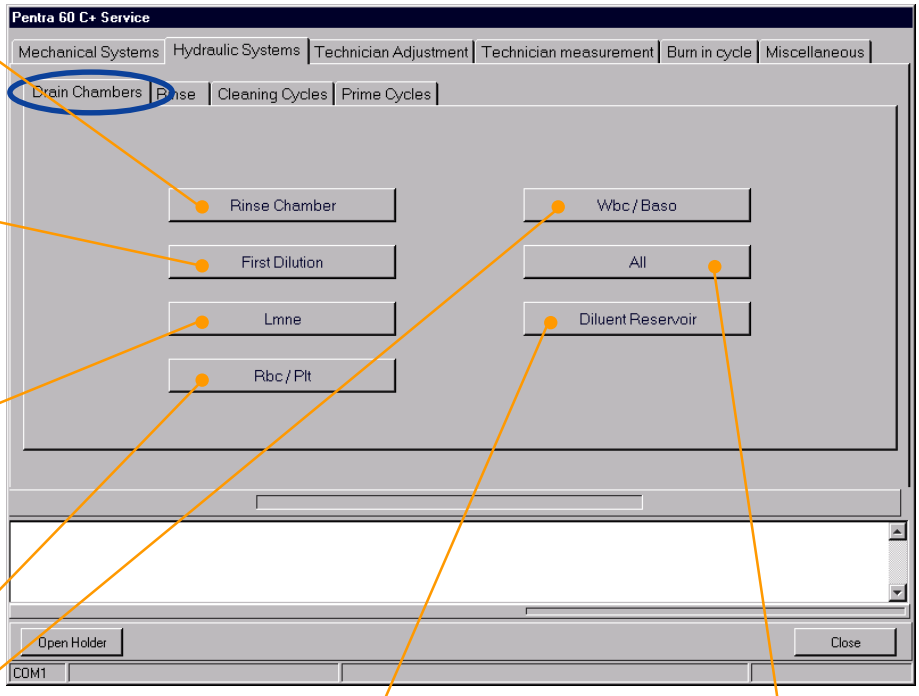
## 2.2. Hydraulics systems

*1- Open «**Menu\Service\Hydraulic Systems**» window:*




### 2.2.1. Drain chambers

• Run Drain chamber cycle if there is a problem with the chambers. From the «**Menu\Service\Hydraulic systems\Drain chamber**» select one of the following options:




+ **Rinse**
• Sampling probe rinsing chamber *(**1**)* drain,

+ **First dilution**
• First dilution chamber *(**2**)* drain,

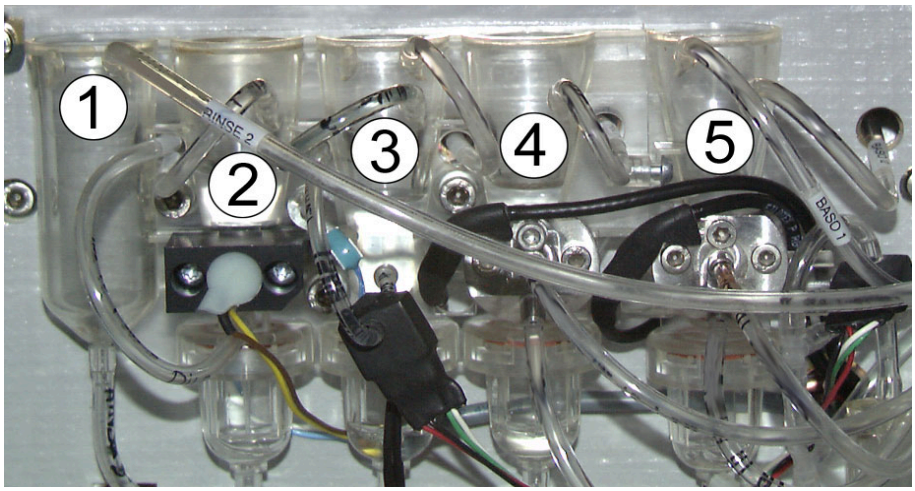
+ **LMNE**
• LMNE chamber *(**3**)* drain,

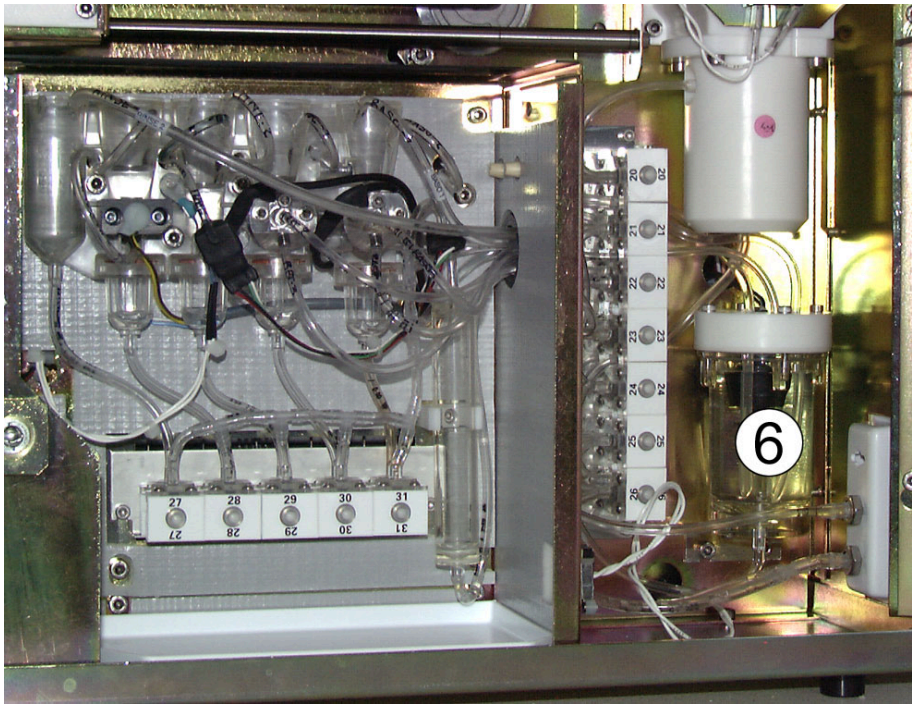
+ **RBC/Plt**
• RBC/Plt chamber *(**4**)* drain,

+ **WBC/BASO**
• WBC/BASO chamber *(**5**)* drain,

+ **Diluent reservoir**
• Diluent reservoir *(**6**)* drain.

+ **All chambers**
• *General drain (**1,2,3,4,5**),*


1
RINSE 2
2
3
4
5
BASO 1


6

## 2.2.2. Rinse

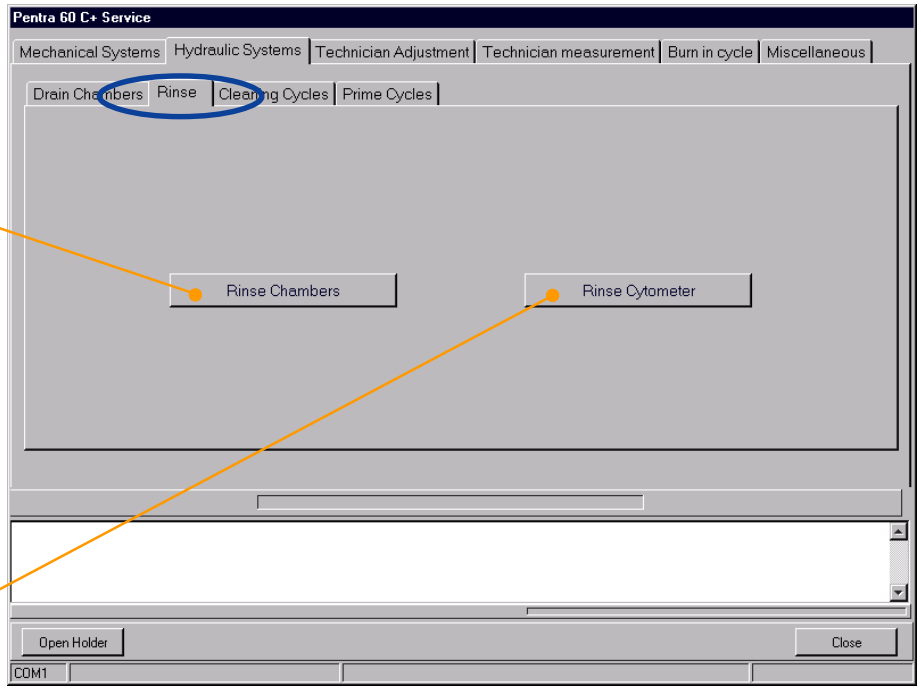
You can rinse instrument's chambers or cytometer with ***ABX Diluent*** from the «**Menu\Service\Hydraulic systems**» select one of the following option:

- Rinse chamber if you have excessive flagging on **CBC** parameters.
- Rinse cytometer to remove bubbles from the flowcell if you have excessive flagging on **5DIFF** parameters.

• *From the «**Menu\Service\Hydraulic systems\Rinse**» select one of the following options:*

+ *ABX **Diluent** is sent to chambers to rinse out these parts.*

+ *ABX **Diluent** is sent to Cytometer to rinse out this part.*



## 2.2.3. Cleaning cycles

- Cleaning cycles are described further.

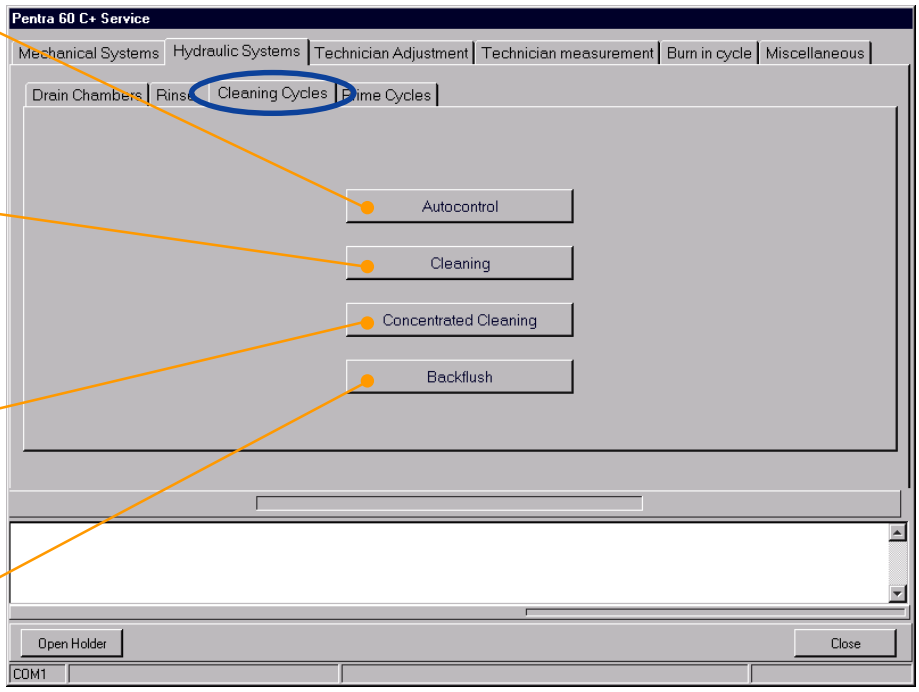
- From the «**Menu\Service\Hydraulic systems\Cleaning Cycles**» select one of the following options:

+ ***Autocontrol*** *cycle: Used principally following the emergency shut down of the instrument for re-initialization and cleaning (cycle evolution bargraph).*

+ ***Cleaning*** *cycle: Cycle required by the instrument after two hours idle (cycle evolution bargraph).*

+ ***Concentrated*** *cleaning: Cycle for cleaning chambers with bleach.*

+ ***Backflush*** *cycle: Cycle for cleaning counting chambers, by counter-pressure, in case of blockage.*

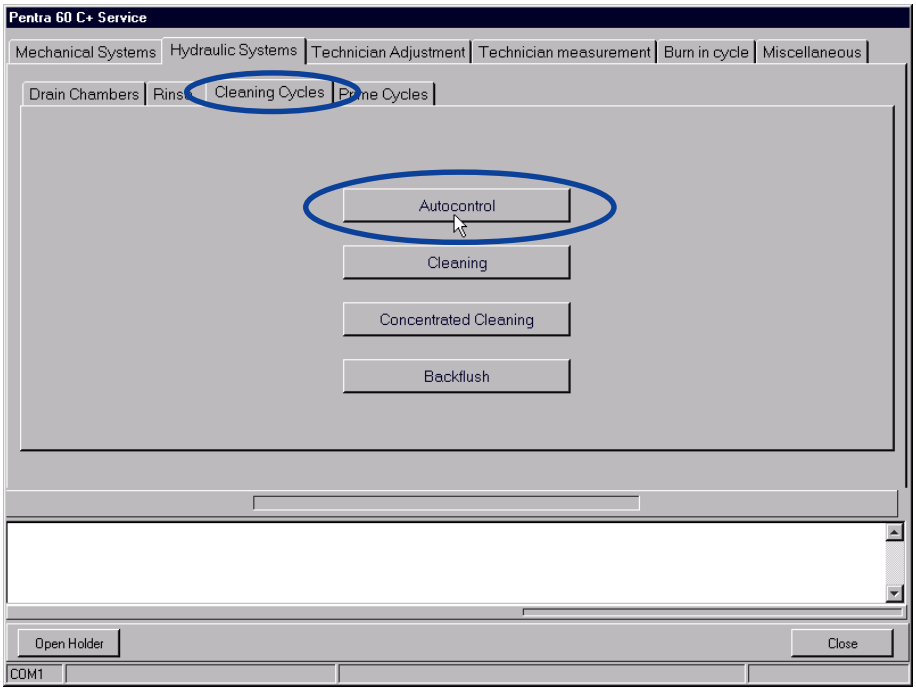


## 2.2.3.1. Autocontrol cycle

• This cycle is required after an emergency stop of the instrument, when a faulty operation has been detected or after a concentrated cleaning.

• Click

button:



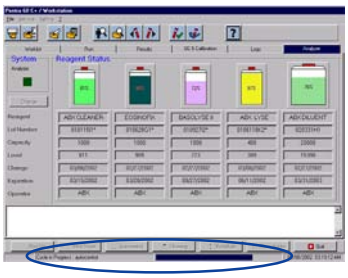

+ ***A** series of mechanical, hydraulic and electronic networks control is performed:*

• *General rinse,*

• *Control of the correct drains of the chambers,*

• *Initialization of the mechanical assemblies.*

+ ***During** cycle progression a status bar is displayed:*

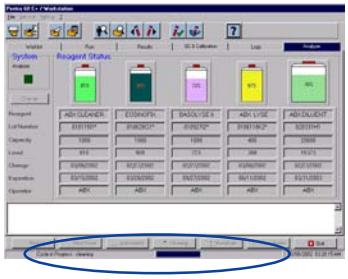


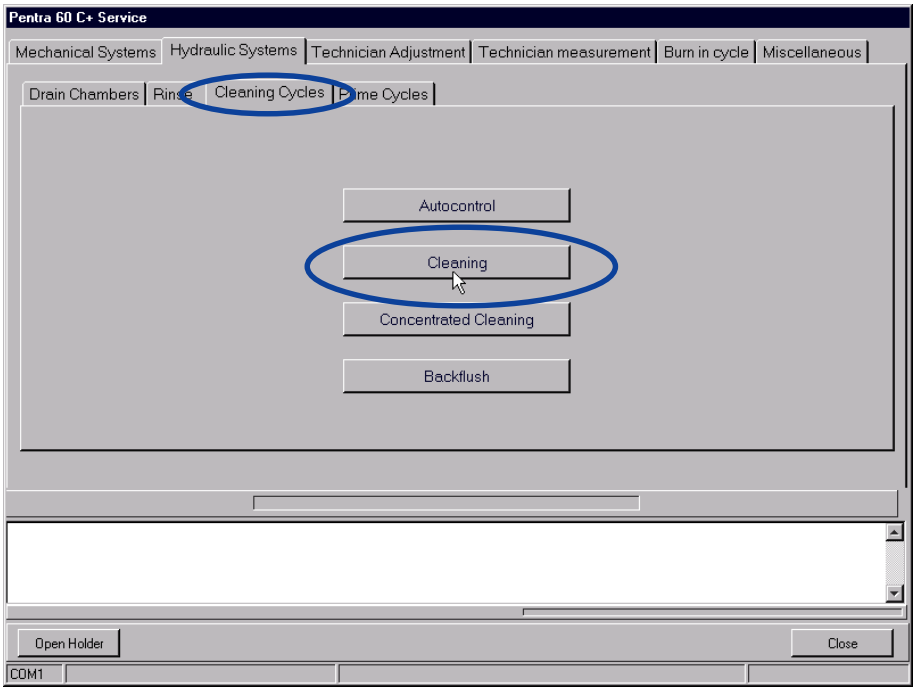
### 2.2.3.2. Cleaning cycle

- This cycle is required by the instrument after two hours idle.
- Click

button:

+ ***During*** *cycle a progression a status bar is displayed:*



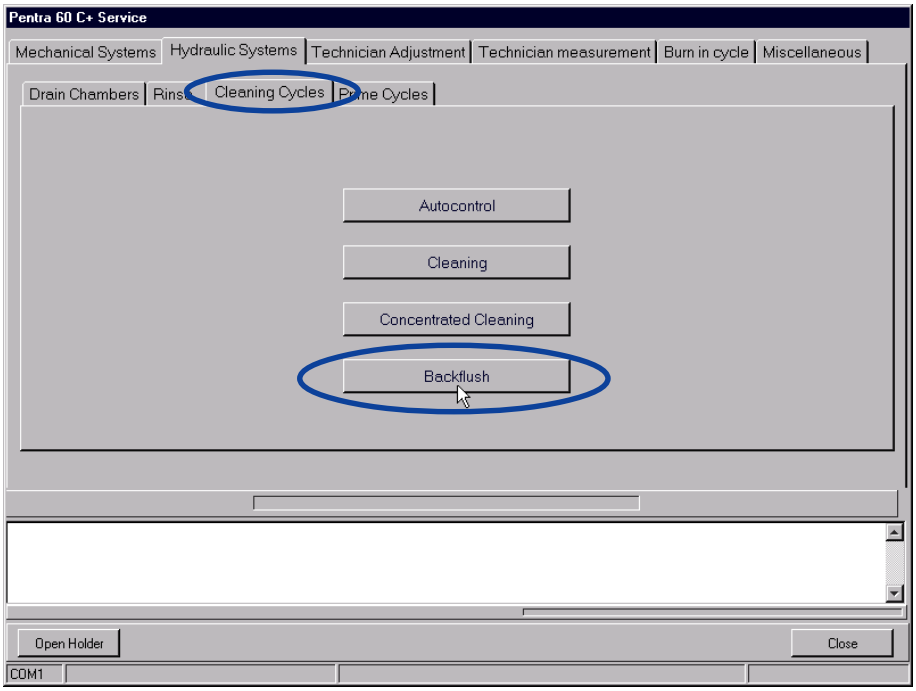



### 2.2.3.3. Concentrated cleaning cycle

- This cycle is for cleaning chambers with bleach.
- Do this procedure if you suspect a clot or fibrin.
- See previous notes on how to perform a concentrated cleaning (paragraph «**Maintenance**»).

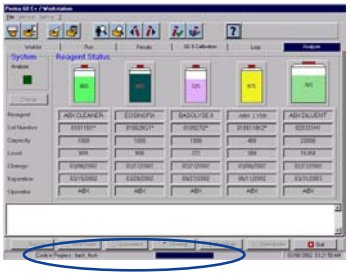
## 2.2.3.4. Backflush cycle

- The backflush cycle delivers pressure through the rear of the apertures to remove blockages.
- Do this procedure if you suspect the apertures are blocked.
- Click on Backflush button:



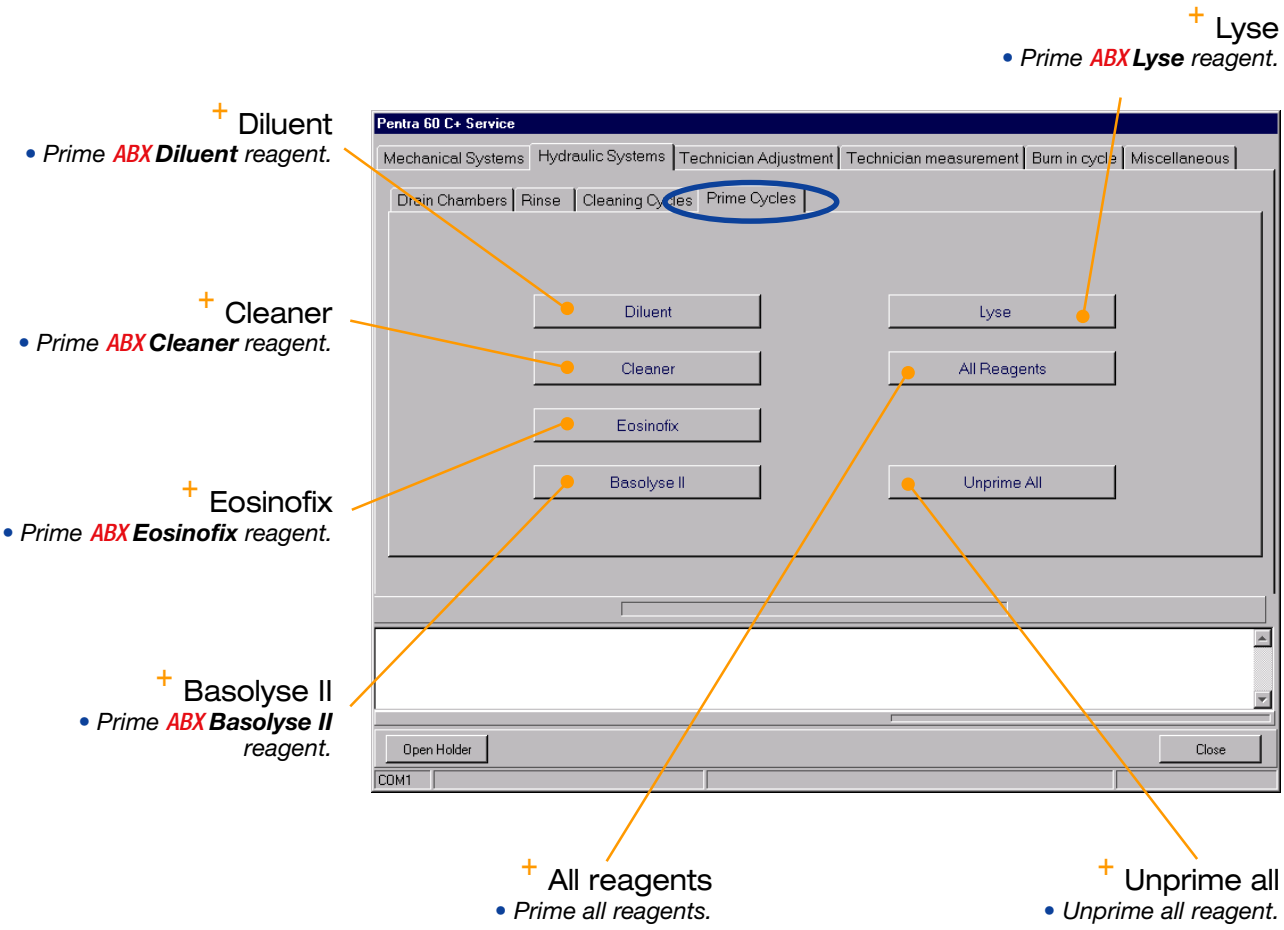

+ ***Delivers*** *pressure through the apertures of the counting chambers to clean them in case of blockages.*

+ ***During*** *cycle a progression a status bar is displayed:*



### 2.2.4. Prime cycles

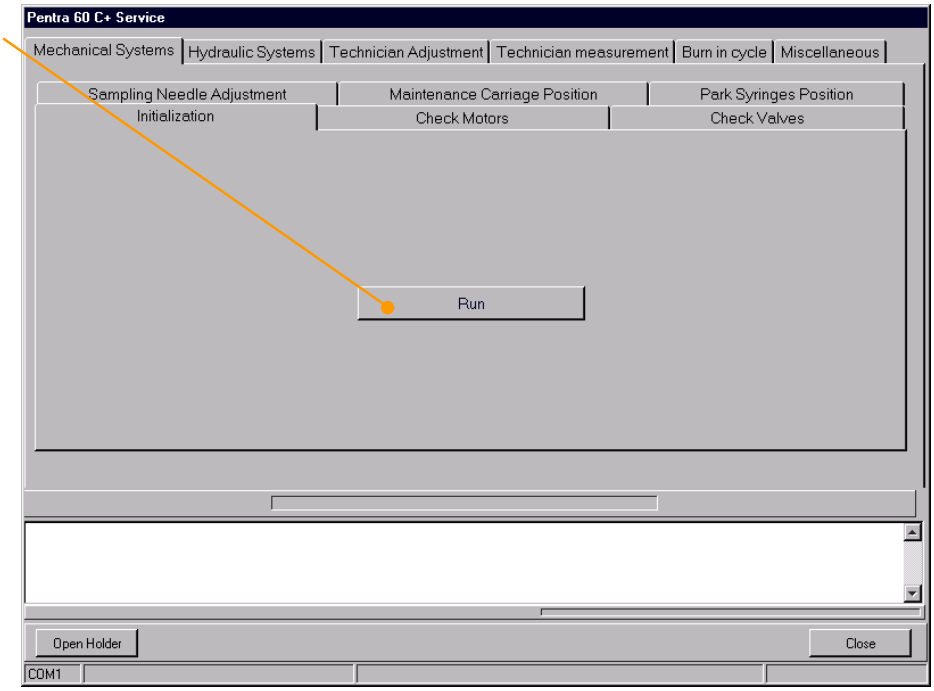
- This function primes reagents into the instrument.
- Do this procedure after service has been performed on the instrument.
- Click on one of these buttons to start the corresponding cleaning cycle:



## 2.3. Mechanical systems

### 2.3.1. Initialization

+ ***All*** *the mechanical assemblies (sampling probe, carriages, syringes....) return to their initial positions, i.e. the operating analysis positions.*



## 2.3.2. Check motors

To control the correct operation of each motor:

• Switch off the instrument.
Open the door (see on previous page) and the left cover of the instrument:

• Loosen the 2 screws of the board support panel and open it.
**Note**: be careful of the flat cables while opening the door !

• Once both sides of the instrument are open, switch on the instrument.
Enter the check motors menu and control each motor pressing the corresponding number.
Right side of the instrument

+ ***Counting syringe***: *Same operation check*

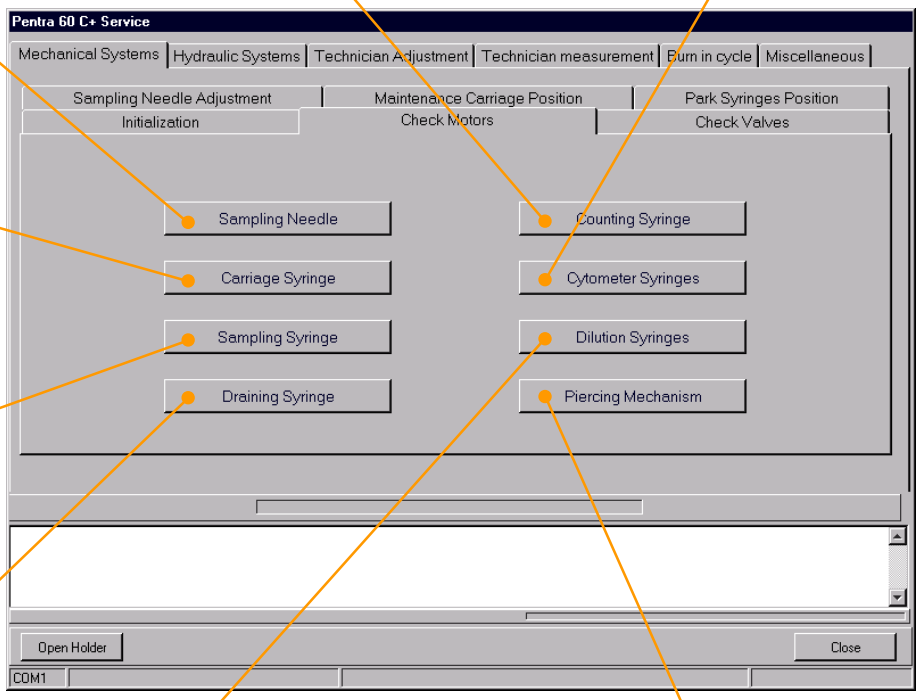
+ ***Cytometer syringes***: *Same operation check*

+ ***Sampling needle***: *check the needle up and down operations. The movements should be smooth and regular.*

+ ***Carriage***: *check the right and left movements of the carriage.*

+ ***Sampling syringe***: *check that the syringe up and down movements are smooth and regular.*

+ ***Draining syringe***: *check the correct up & down movements of the syringe.*
*Left side of the instrument*




+ ***Dilution syringes***: *Same operation check*

+ ***Piercing mechanism***: *Same operation check*

## 2.3.3. Check valves

To control the correct operation of the valves:

- Open the door (see on previous pages) and the left cover of the instrument.
- The valves can be operated pressing the corresponding number of the assembly.
- Closely observe the valve operations; the movements have to be straight and regular.

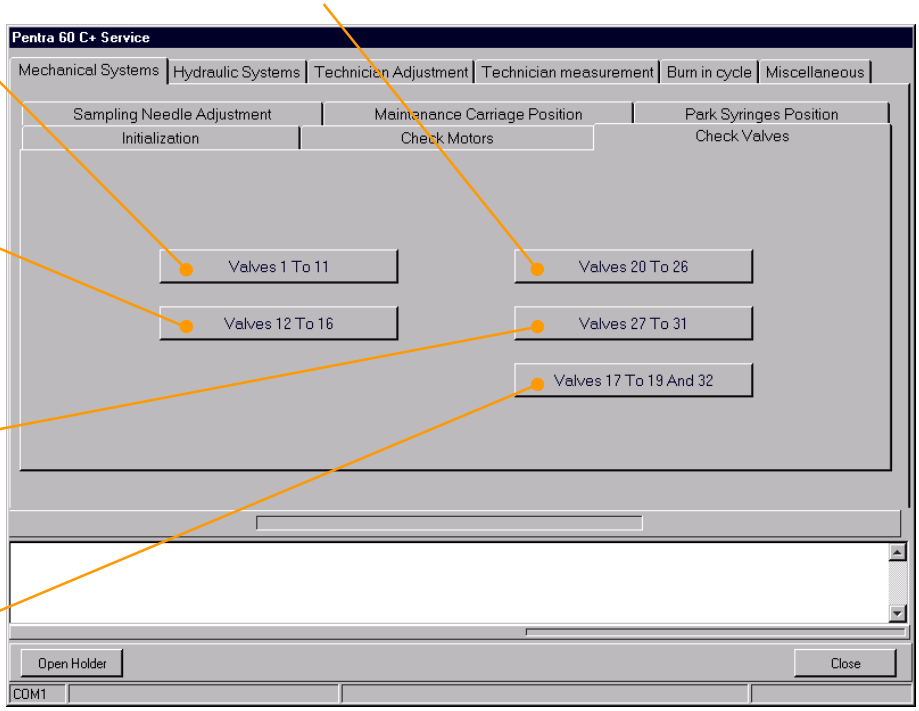
+ ***Valves 20 to 26**: Check correct operation for these valves.*

+ ***Valves 1 to 11**: Check correct operation for these valves.*

+ ***Valves 12 to 16**: Check correct operation for these valves.*

+ ***Valves 27 to 31**: Check correct operation for these valves.*

+ ***Valves 17 to 19 & 32**: Check correct operation for these valves.*

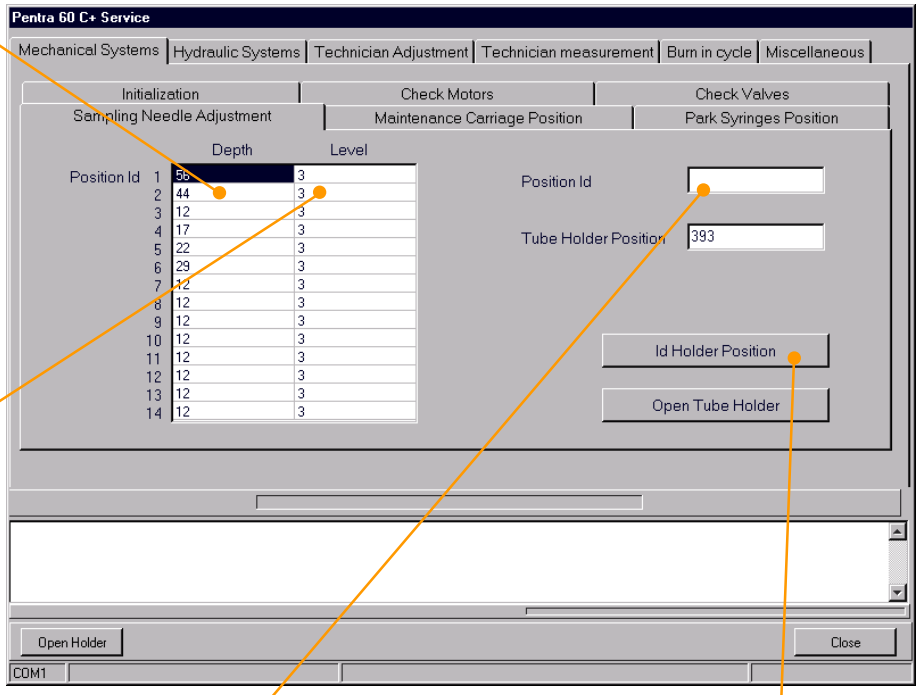


## 2.3.4. Sampling needle adjustment

- Tube holder and sampling needle positions are factory adjusted, do not modify them.

+ ***Hole** depth, in milimeters, for each tube holder position Id.*

+ ***Level** of probe sampling in milimeters from the tube holder's bottom.*



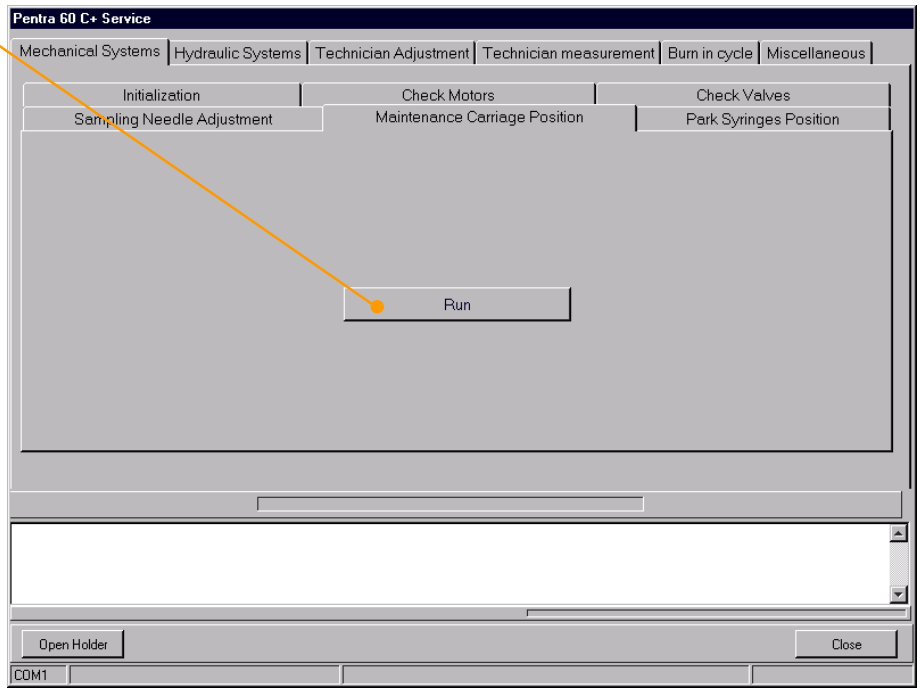

+ ***Position** Id field returns the tube holder position after an «**Id holder position**» command.*

+ ***Id** holder position button returns the actual «**Position Id**» of the tube holder after you close it (Click Open tube holder button to open it again).*

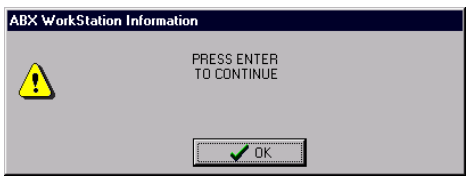
## 2.3.5. Maintenance carriage position

• Carriage shift cycle over the trays to simplify maintenance operations such as the replacement of a sampling needle for example.

+ ***Run**: Moves sampling carriage to maintenance position.*



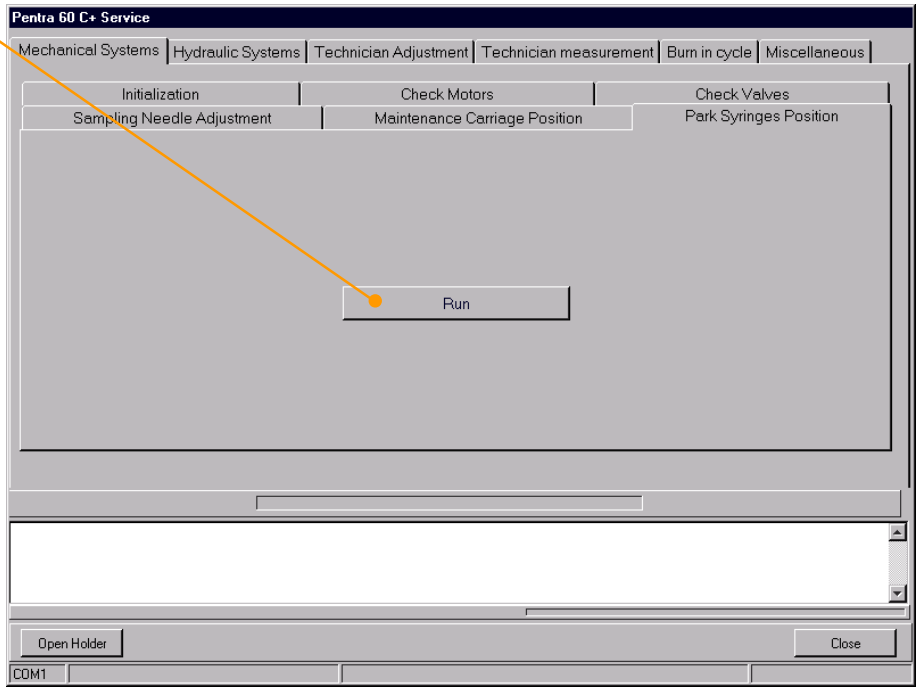

+ ***Press** enter or click* OK *button to return to initial position.*



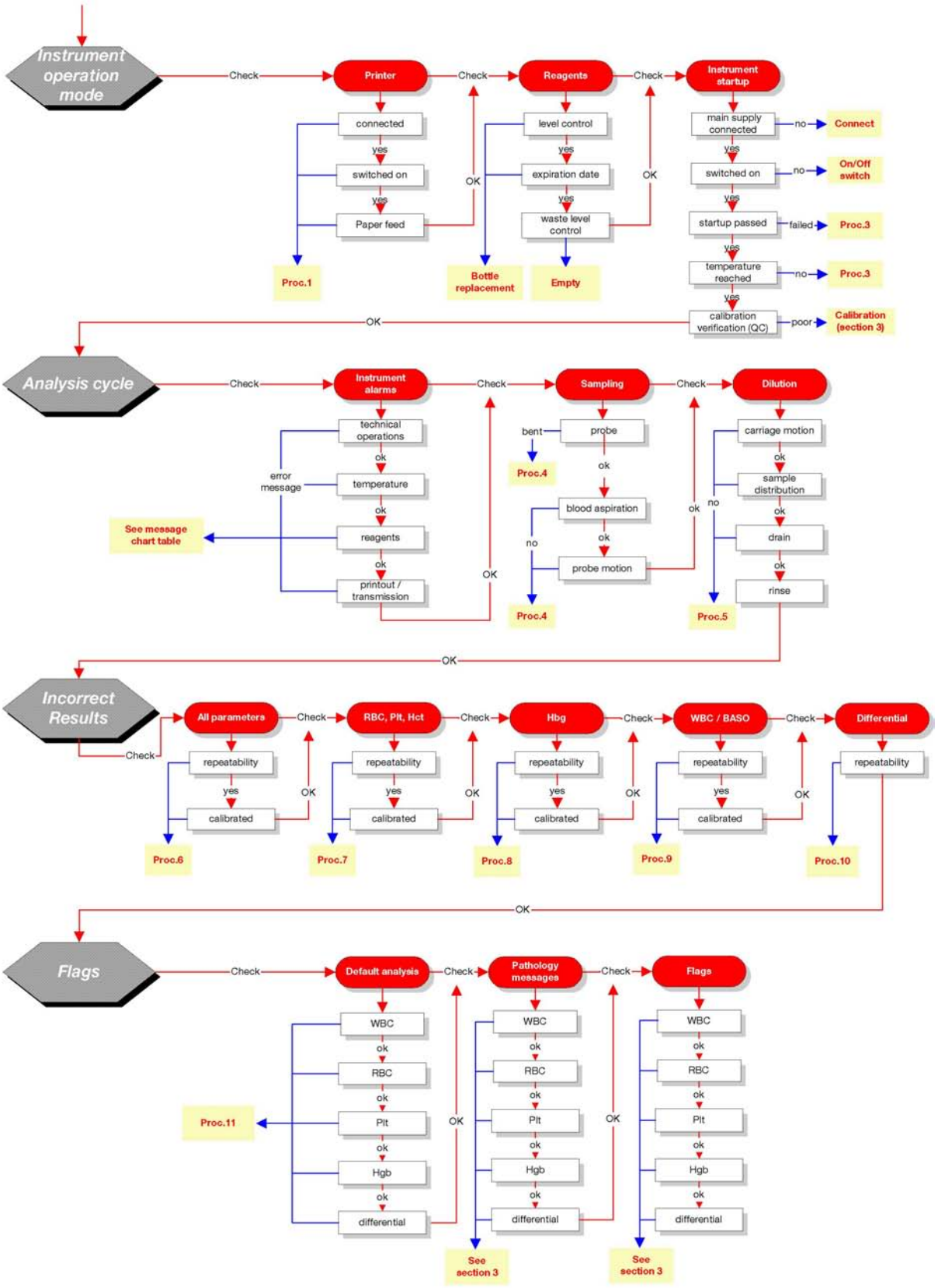
## 2.3.6. Park syringe position

• This function parks syringes when the instrument will not be used for a long period of time or for transportation:

+ ***Run**: Moves syringes to park position.*



# 3.TROUBLESHOOTING



## 3.1. Instrument operation mode

◆ Procedure 1
*Printer*

- See printer user manual to connect, to switch on/off or to feed paper.

◆ Procedure 2
*Workstation computer*

- See computer user manual to connect or to switch on/off workstation.

◆ Procedure 3
*Reagents*

- Bottle replacement (see *Chapter 4. Instrument configuration*),
- Waste container: empty and neutralize as recommended in *Chapter 1. Specifications*.

◆ Procedure 4
*Instrument Startup*

***Startup failed:***

- Check the reagent expiration dates: replace bottle if necessary,
- Re-run a startup,
- perform an auto-concentrated cleaning (*Chapter 5. Maintenance & Troubleshooting*).

***Temperature not reached:***

- Wait for 5 minutes to reach the operating temperature, if temperature is not reached call your *ABX DIAGNOSTICS* **Representative Service Department**.

***Calibration verification out of the acceptable limits***

- Clean the system see *Chapter 5. Maintenance & Troubleshooting* and rerun the control,
- Run a new vial,
- Calibrate the instrument (see *Chapter 4. Instrument configuration*).

## ◆ Procedure 5
*Sampling Probe*

***Sampling probe***

• Check the motion of the probe: «**Menu\Service\Mechanical systems\Check motors\Sampling needle**».
• Open the pneumatic access door.
• Run an analysis cycle on blood.
• Control the specimen aspiration (blood delivered in the chambers).
• Check the probe is not bent.

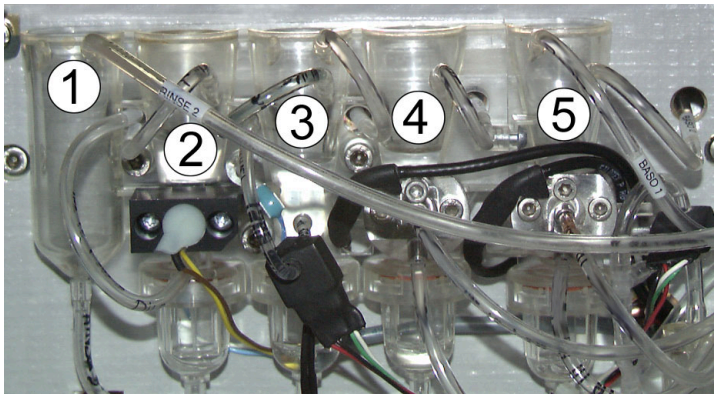
## ◆ Procedure 6
*Dilution*

***Carriage motion***

• Check that hydraulic operations appear to work properly (reagent level in each chamber, carriage motion).

***Sample distribution:***

• Run an analysis cycle and check that the specimen distribution is performed correctly into the chambers.
• A probe rinse is previously carried out in the rinse chamber (**1**) (blood appears in this chamber).
• The first specimen is delivered to the first dilution chamber (**2**) (brown colour), the second to the WBC/BASO chamber (**5**) (clearer) and the third one to the LMNE chamber (**3**) (the darkest).
• Check that bubbling is provided to these chambers once the specimen have been diluted.




***Drain and rinse***

• Check the chambers are drained and rinsed.

• If operations are faulty, identify the source of the malfunction and call your *ABX DIAGNOSTICS* **Representative Service Department.**

## 3.2. Results

### ◆ Procedure 7
*All Parameters*

***Repeatability (according to the CV Specifications see** Chapter 1. Specifications**)***

- Is the instrument non repeatable on all parameters?

if not perfom directly the procedure corresponding to the non repeatable parameter.

- If all parameters are not repeatable:
- Visually check that the sampling operation appears to be correct.
- Control the sampling syringe operations (see *Chapter 5. Maintenance & Troubleshooting*)
- Control the counting syringe operations (see *Chapter 5. Maintenance & Troubleshooting*)
- Perform an autoconcentrated cleaning

- If all these operations appear to be correct, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***Calibration***

- If the system appears to be operating properly, fresh uncontaminated reagents are being used and the precision is within the specifications, the *ABX PENTRA 60 C+* may need a calibration as described *Chapter 4. Instrument configuration*

### ◆ Procedure 8
*RBC, Plt, Hct*

***Repeatability***

- If RBC, Plt & Hct are not repeatable:
- Check the second dilution is carried out correctly (sample from the chamber 2 to the chamber 4),
- Check the Bubbling in the RBC/Plt chamber (4) once the dilution is carried out (the dilution remains transparent),
- Perform an autoconcentrated cleaning.

- If all these operations appear to be correct, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***Calibration***

- *See procedure 7*

## Procedure 9 *Hgb*

***Repeatability***

- Is the instrument non repeatable on Hgb ?
- Run a analysis cycle,
- Check the dilution colour in the chamber (2): «Milky» when the sample is first delivered to the chamber, then brown transparent when Lyse is injected,
- Perform an autoconcentrated cleaning.

- If this does not correct the Hgb count, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***Calibration***

- *See procedure 7*

## Procedure 10 *WBC, BASO*

***Repeatability***

- Is the instrument non repeatable on WBC/BASO ?
- Perform an autoconcentrated cleaning.

- If this does not correct the Hgb count, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***Calibration***

- *See procedure 7*

## Procedure 11 *Differential*

***Repeatability***

- Is the instrument non repeatable on differential ?
- Perform an autoconcentrated cleaning.

- If this does not correct the WBC/BASO count, call your *ABX DIAGNOSTICS* **Representative Service Department.**

## 3.3. Flags

◆ Procedure 12
Default analysis

***WBC***

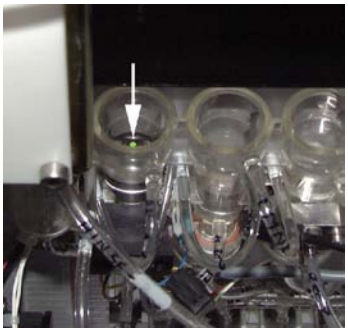
- Perform an autoconcentrated cleaning,
- Rerun the specimen,
- Check the operation of the liquid valve <23> and <14> (opening and closing during the cycle). If defective, replace the valve.

- If it does not correct WBC results, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***RBC, Plt***

- Perform an autoconcentrated cleaning,
- Rerun the specimen,
- Observe the operation of the liquid valve <14> (opening and closing during the cycle). If not replace the valve.

- If it does not correct the RBC or Plt results, call your *ABX DIAGNOSTICS* **Representative Service Department.**



***Hgb***

- Is the Hgb LED illuminated when the system power is on ?
- If not call your*ABX DIAGNOSTICS* **Representative Service Department**, if it is continue:
- Perform an autoconcentrated cleaning,
- Rerun the specimen.

- If it does not correct the Hgb results, call your *ABX DIAGNOSTICS* **Representative Service Department.**

***Differential***

- Confirm that the lamp is lit when the instrument is on. If not replace it as described below,
- Run a cytometer rinse (see *Chapter 5. Maintenance & Troubleshooting*),
- Re-run the specimen.

- If it does not correct the LMNE results, call your *ABX DIAGNOSTICS* **Representative Service Department.**

# 4. ERROR MESSAGES

## 4.1. Printer

| Messages | Causes | User Actions |
|---|---|---|
| The printer is disconnected, switched OFF or has not been selected | Printout operations disabled | Switch ON<br>Press «ON LINE»<br>See the printer user's manual |

## 4.2. Calibration

| Messages | Causes | User Actions |
|---|---|---|
| Access denied | Incorrect password entered by operator | Enter correct password |
| Illegal date | Incoherent date entered by operator | Enter correct date |
| Minimum tagged CBC incorrect. X at least 3. | Selected results for calibration calculation | Select at least 3 results |
| Target file QC incorrect version | Bad file format or bad disk | Replace the disk |
| Target QC File Not Found | Bad file format or bad disk | Replace the disk |
| Target QC File Read Error | Bad file format or bad disk | Replace the disk |
| Target QC file unknown error | Bad file format or bad disk | Replace the disk |
| Calibration Failed :<br>Coef. Out Of Range | Bad result | Restart calibration |
| Calibration Failed :<br>Confirm To Force Calibration | Bad result | Restart calibration |

## 4.3. Temperature

| Messages | Causes | User Actions |
|---|---|---|
| Temperature out of range | Thermic regulation problem | Call your *ABX DIAGNOSTICS* representative Service Department |
| Heating coil initialization | Operating temperature not reached | Wait for a few minutes |

## 4.4. Reagents

| Messages | Causes | User Actions |
|---|---|---|
| No diluent, check level | Diluent reservoir empty | Replace the diluent container (see *Chapter 5. Maintenance & Troubleshooting*) |
| Reagent low level (reagent name) | none | Replace the reagent bottle (see *Chapter 5. Maintenance & Troubleshooting*) |
| Reagent low level | Message triggered at the end of the startup | Control the reagent levels / replace it |
| Drain time out | Draining problems | Call your *ABX DIAGNOSTICS* representative Service Department |

## 4.5. Miscellaneous

| Messages | Causes | User Actions |
|---|---|---|
| Emergency stop, run an Autocontrol | Blocked motor<br>Incorrect drains<br>Thermal door opended | Control the motor operations Menu\Service\Mechanical systems\Check motors |
| ..... not reaching home | Blocked motor | |
| Thermal door opened | Open during a cycle | Close the door and rerun sample |
| Illegal time | Incoherent time entered by operator | Enter correct time |
| Data not saved, value out of range | Incorrect value entered by operator | Enter correct value |
| User password | Password required to carry out an operation | Enter password |
| Bad reference position | Mechanical problem | Call your *ABX DIAGNOSTICS* representative Service Department |
| Language of Pentra changed, please restart the computer and instrument | Language has changed | Restart Instrument and Worstation |

# 5. HAZARDS RELATING TO OPERATOR SAFETY & INSTRUMENT FUNCTION

• Hazards relating to operator safety / instrument function (injury or instrument damage which may occur during instrument operation or maintenance) are indicated by special conditions. Descriptions of these conditions are given in the first pages of the *ABX PENTRA 60 C+* manual.

• The normal operation of the *ABX PENTRA 60 C+* instrument must be done with the protection cover on in order to prevent injuries.

• During maintenance procedures or instrument checks, the instrument must be switched off and the power cable removed.

• The main hazards are given in the following 2 tables and are described as:

## 5.1. Hazards relating to instrument function

| Undesirable Effects | Possible Causes | Instrument Response | User Action |
|---|---|---|---|
| Incorrect mechanical operation | Defective stepper motors | Motor alarms<br>Current cycle stops | Autocontrol cycle |
| Incorrect hydraulic operation | Leaks or blockages | Reagent alarms<br>Current cycle stops | Autocontrol cycle<br>Startup cycle<br>Prime reagent cycle |
| Incorrect optical operation | Defective optical parts<br>Optical parts dirty | Specific flags<br>Blanck cycle measurements outside acceptable limits | Autocontrol cycle<br>Cleaning cycle<br>Autoconcentrated cleaning cycle |
| Incorrect electrical operation | Incorrect main supply voltage | No instrument initialization | Check main voltage |

## 5.2. Hazards relating to operator safety

| Undesirable Effects | Possible Causes | Instrument Response | User Action |
|---|---|---|---|
| Injury by sampling probe | Attempt to run sample during a non authorized period | Cycle start rejected | Refer to the manual<br>sampling control LED indications<br>Read the concerned documentation |
| Electrical hazards in general | Contacts with internal electrical parts of the instrument | No electrical contact possible during normal operation - Instrument grounded during installation | Read and follow the mentioned recommandation |
| Contact with reagents | Direct contact with reagents<br>Leaks during operation checked during cycles | Integrated reagents<br>Automatic aspiration and waste<br>Liquid transfer | Follow the reagent handling recommendations given in Chapter 1 |
| Contact with infectious samples | Direct contact with blood or with contaminated parts | Automatic cleaning of the parts | Read and follow the mentioned recommendation |
| | Contact with waste products | Automatic waste disposal | Follow the laboratory regulations |

# ANNEX

GLOSSARY ..... ANNEX-2

LIST OF ABBREVIATIONS ..... ANNEX-4

WORKLIST'S KEYBOARD SHORTCUTS ..... ANNEX-6

PNEUMATIC DIAGRAM ..... ANNEX-7

# GLOSSARY

| | Definition |
|---|---|
| accuracy | Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value |
| *agglutination* | *Clump* |
| background count | Measure of the amount of electrical or particle interference |
| *blank cycle* | *Runs diluent through the system to clean it out* |
| calibration | A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors |
| *calibration factors* | *These are correction factors that the system uses to fine-tune instrument accuracy* |
| calibrator | A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust measurement |
| *carryover* | *The amount, in percent, of blood cells remaining in diluent following the cycling of a blood sample* |
| cell control | A preparation made of human blood with stabilized cells and surrogate material used for dailyinstrument quality control |
| *characteristics* | *See performance characteristics* |
| coefficient of variation | An expression in percent of data (SD) spread related to the mean CV%=(SD/mean)x100 |
| *control* | *A substance used for monitoring the performance of an analitycal process or instrument* |
| CV | See Coefficient of variation |
| *default* | *An original factory setting* |
| expiration date | The last day that you can use that specific lot number of reagent, control or calibrator |
| *fL* | *Abbreviation for femtoliter* |
| femtoliter | One quadrillionth ($10^{15}$) of a liter |
| *field* | *An area on a screen for entering data* |
| flags | on printouts or screens, letters or symbols that appear next to parameter results to indicate specific conditions |
| *linearity* | *The ability of an instrument to recover expected results (reference va lues or calculated values) for such parameters as WBC, RBC, Hgb and Plt, at varying levels of concentration of these parameters within specified limits* |

| | |
|---|---|
| lot number | A manufacturer's code that identifies products such as reagents, controls or calibrators |
| *mean* | *Arithmetic average of a group of data* |
| operating range | Range of results over which the instrument displays, prints and transmits data |
| *parameter* | *A component of blood that the instrument measures and reports* |
| performance | Actual performance of the instrument characteristics |
| *performance* | *Targeted performance of the instrument based on established ranges and parameters specifications* |
| quality control (QC) | A comprehensive set of of procedures a laboratory establishes to ensure that the instrument is working accurately and precisly |
| *reproducibilty* | *This procedure checks that the system gives similar results (within established limits) every time it measures the same sample* |
| SD | A measure of variation within a group samples or within a population (standard deviation) |
| *shutdown cycle* | *Cleans the instrument's fluidic lines and apertures to help prevent residue buildup* |
| specifications | see performance specifications |
| *startup cycle* | *Ensures that the instrument is ready to run; includes performing a background test* |
| verification | Procedure to analyze cell controls or whole blood with known values to determine if your results are within the acceptable range |
| *whole blood* | *Non-diluted blood; blood and anticoagulant only* |

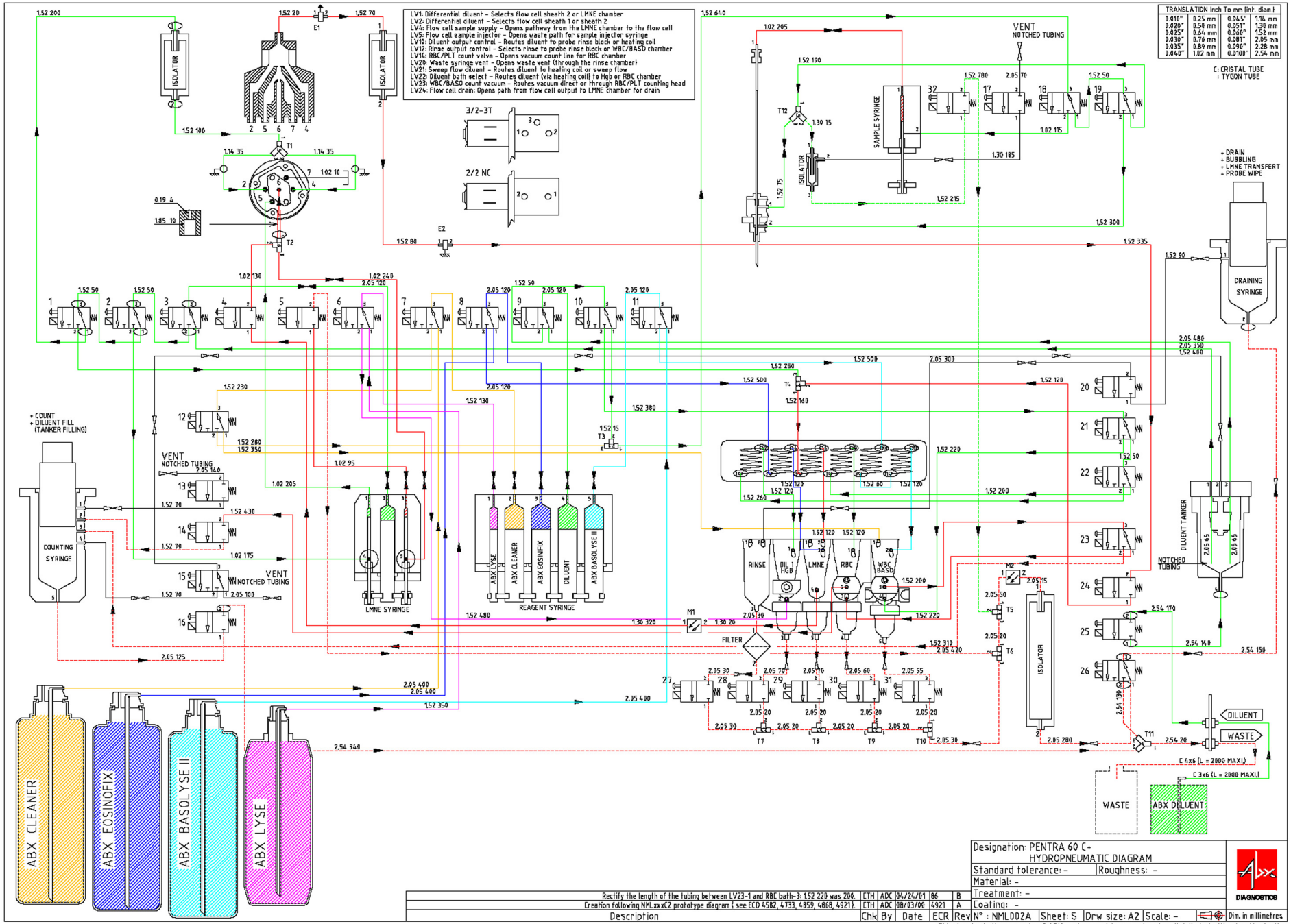
# LIST OF ABBREVIATIONS

| Abbrevitaion | Meaning |
|---|---|
| µL | microliter |
| *µm* | *micrometer* |
| ACD | acid-citrate-dextrose |
| *ALY* | *Atypical Lymphocyte* |
| BAS or BASO | basophil |
| *bps* | *bit per second* |
| CBC | cell blood count |
| *Cl* | *chlorine* |
| cm | centimeter |
| *CV* | *coefficient of variation* |
| DHSS | double hydrodynamic sleeving |
| *diff* | *differential* |
| dL | deciliter |
| *EDTA* | *ethylenediaminetetraacetic acid* |
| EOS | eosinophil |
| *fL* | *femtoliter* |
| ft | foot or feet |
| *g* | *gram* |
| Gb | gigabyte |
| *Hct* | *hematocrit* |
| Hgb | hemoglobin |
| *Hz* | *hertz* |
| L | liter |
| *lb* | *pound* |
| LED | light-emitting diode |
| *LIC* | *Large Immature Cell* |
| LYM | lymphocyte |
| *m* | *meter* |
| mb | millibar |
| *Mb* | *megabyte* |
| MCH | mean corpuscular hemoglobin |
| *MCHC* | *mean corpuscular hemoglobin concentration* |
| MCV | mean corpuscular volume |
| *MDSS* | *multi distribution sampling system* |
| MHz | megahertz |
| *mL* | *milliliter* |
| mm | millimeter |

| | |
|---|---|
| *MON* | *monocyte* |
| MPV | mean platelet volume |
| *MSDS* | *material safety data sheet* |
| n | number |
| *NEU* | *neutrophil* |
| nm | nanometer |
| *Pct* | *Plateletcrit* |
| PDW | Platelet Distribution Width |
| *Plt* | *platelet* |
| RBC | red blood cell |
| *RDW* | *red distribution width* |
| SD | standard deviation |
| *VA* | *voltampere* |
| Vac | volt alternatif current |
| *WBC* | *white blood cell* |

# WORKLIST'S KEYBOARD SHORTCUTS

| KEYBOARD SHORTCUT | RESPONSE |
|---|---|
| Ctrl + click | Selection of a line or multiple lines. |
| *Ctrl + Shift + click* | *Only active for performed analyses: Block selection by marking the beginning and then the end.* |
| Alt + click | Only active for performed routine analyses: Displays the result. |
| *Double click* | *Switching between list and sheet.* |
| Arrow up | Goes to the previous line. |
| *Ctrl + Arrow up* | *Goes to the first line of the grid .* |
| Arrow down | Goes to the line following **creation of a new entry** of the worklist if on the last line. |
| *Ctrl + Arrow down* | *Goes to the last line.* |
| Page up | Goes up to number of lines displayed in the grid. Cancels the line selection. |
| *Ctrl +Page up* | *Goes to the first line of the grid. Cancels the line selection.* |
| Page down | Goes down to number of lines displayed in the grid. Cancels the line selection. |
| *Arrow left* | *Moves one column to the left.* |
| Ctrl + Arrow left | Goes to the first line of the column of the line in progress. |
| *Arrow right* | *Moves one column to the right.* |
| Ctrl + Arrow right | Goes to the last column of the line in progress. |
| *Shift + Arrow down* | *Downward selection of several records.* |
| Shift + Arrow up | Upward selection of several records. |
| *Home* | *Goes to the first column of the line in progress.* |
| Ctrl + Home | Goes to the first record of entire data set. Cancels the line selection. |
| *End* | *Goes to the last column of the line in progress.* |
| Ctrl + End | Goes to the last record of entire data set. Cancels the line selection. |
| *Tab* | *Goes to the next cell in the grid.* |
| Shift + Tab | Goes to the previous cell in the grid. |
| *Ctrl + Delete* | *Deletes the selection in progress.* |
| Insert | Inserts a new line below the line in progress and is positioned below. Cancels the line selection. |
| *Escape* | *Cancels unsent modifications. Cancels the line selection.* |


LV1: Differential diluent – Selects flow cell sheath 2 or LMNE chamber
LV2: Differential diluent – Selects flow cell sheath 1 or sheath 2
LV4: Flow cell sample supply – Opens pathway from the LMNE chamber to the flow cell
LV5: Flow cell sample injector – Opens waste path for sample injector syringe
LV10: Diluent output control – Routes diluent to probe rinse block or heating coil
LV12: Rinse output control – Selects rinse to probe rinse block or WBC/BASO chamber
LV14: RBC/PLT count valve – Opens vacuum count line for RBC chamber
LV20: Waste syringe vent – Opens waste vent (through the rinse chamber)
LV21: Sweep flow diluent – Routes diluent to heating coil or sweep flow
LV22: Diluent bath select – Routes diluent (via heating coil) to Hgb or RBC chamber
LV23: WBC/BASO count vacuum – Routes vacuum direct or through RBC/PLT counting head
LV24: Flow cell drain: Opens path from flow cell output to LMNE chamber for drain
TRANSLATION Inch To mm (int. diam.)
0.010" 0.25 mm 0.045" 1.14 mm
0.020" 0.50 mm 0.051" 1.30 mm
0.025" 0.64 mm 0.060" 1.52 mm
0.030" 0.76 mm 0.081" 2.05 mm
0.035" 0.89 mm 0.090" 2.28 mm
0.040" 1.02 mm 0.0100" 2.54 mm
C: CRISTAL TUBE
: TYGON TUBE
+ DRAIN
+ BUBBLING
+ LMNE TRANSFERT
+ PROBE WIPE
+ COUNT
+ DILUENT FILL
(TANKER FILLING)
VENT
NOTCHED TUBING
ISOLATOR
SAMPLE SYRINGE
DRAINING SYRINGE
COUNTING SYRINGE
LMNE SYRINGE
REAGENT SYRINGE
ABX LYSE
ABX CLEANER
ABX EOSINOFIX
DILUENT
ABX BASOLYSE II
RINSE
DIL 1 HGB
LMNE
RBC
WBC BASO
FILTER
DILUENT TANKER
3/2-3T
2/2 NC
E1
E2
T1
T2
T3
T4
T5
T6
T7
T8
T9
T10
T11
T12
M1
M2
DILUENT
WASTE
ABX DILUENT
C 4x6 (L = 2000 MAX)
C 3x6 (L = 2000 MAX)

| Description | Chk | By | Date | ECR | Rev |
|---|---|---|---|---|---|
| Rectify the length of the tubing between LV23-1 and RBC bath-3: 1.52 220 was 200. | CTH | ADC | 04/24/01 | 86 | B |
| Creation following NML xxxC2 prototype diagram ( see ECD 4582, 4733, 4859, 4868, 4921). | CTH | ADC | 00/03/00 | 4921 | A |

Designation: PENTRA 60 C+
HYDROPNEUMATIC DIAGRAM
Standard tolerance: – | Roughness: –
Material: –
Treatment: –
Coating: –
N° : NML002A | Sheet: S | Drw size: A2 | Scale: – | Dim. in millimetres

This drawing is the property of ABX, and may not be reproduced or distributed without authorization

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Diluent

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Micros 60 | |
| ABC Vet | |
| Micros CRP | |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | ✓ |
| Pentra 120 Retic | ✓ |
| Pentra DX 120 | ✓ |
| Slide Preparation System | |

12/05/03
A95A00005-A

REF 0901020 (20L)

REAGENT 20L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Buffered isotonic solution for sheating and diluting leucocytes, and for the determination and differentiation of blood cells, and the measurement of hematocrit on ABX blood cell counters

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & expiration

**Storage conditions:** Stored at 18 to 25°C and away from the light.

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & handling precautions

**Composition**:
Sodium Chloride . . . . . .< 1 %
Natriumazid.. . . . . < 0,1 %
Surfactant . . . . . .< 0,1 %

**pH**: 8,1 +/- 0,2 (T = 20°C)

**Resistivity**: 60,5 +/- 1 Ω (T = 20°C)

**Description**: Limpid and odourless aqueous solution.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument User Manual.

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

Explore the future

HORIBA GROUP

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Cleaner

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Micros 60 | |
| ABC Vet | |
| Micros CRP | |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | ✓ |
| Pentra 120 Retic | ✓ |
| Pentra DX 120 | ✓ |
| Slide Preparation System | |

12/05/03
A95A00012-A

REF 0903010 (1L)

REAGENT 1L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Enzymatic solution with proteolytic action for the cleaning of ABX blood cell counters.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & Expiration

**Storage conditions**: Stored at 18°C (65°F) to 25°C (77°F).

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connexion» in the instrument User Manual.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & Handling precautions

**Composition**:
Organic Buffer . . . . . < 0,2 %
Proteolytic Enzyme . . < 0,2 %

**pH**: 9,6 +/- 0,4 (T = 20°C)

**Resistivity**: 72 +/- 2 Ω (T = 20°C)

**Description**: Transparent liquid.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument User Manual.

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual.

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

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Explore the future

HORIBA GROUP

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Eosinofix

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Argos/Helios (5diff) | ✓ |
| Micros 60 | |
| ABC Vet | |
| Micros CRP | |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | ✓ |
| Pentra 120 Retic | ✓ |
| Pentra DX 120 | |
| Slide Preparation System | |

12/05/03
A95A00003-A

REF 0206010 (1L)

REAGENT 1L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Reagent for differentiation of leucocyte subpopulations on ABX blood cell counters.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & expiration

**Storage conditions**: Room temperature between 18°C (65°F) to 25°C (77°F).

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & handling precautions

**Composition**:
Propane 1,2 diol . . . . . 3 %
Formic Dye . . . . . 0,004 %

**pH**: 6,9 +/- 0,1 (T = 20°C)

**Resistivity**: 57 +/- 3 Ω (T = 20°C)

**Description**: Deep blue aqueous solution, smells of alcohol.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument User Manual.

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual.

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Basolyse II

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Micros 60 | |
| ABC Vet | |
| Micros CRP | |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | |
| Pentra 120 Retic | |
| Pentra DX 120 | |
| Slide Preparation System | |

12/05/03
A95A00002-A

REF 0906003 (1L)

REAGENT 1L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Erythrocyte lysing reagent for white blood cell counting and basophil differentiation on ABX blood cell counters.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & expiration

**Storage conditions**: Room temperature between 18°C (65°F) to 25°C (77°F).

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & handling precautions

**Composition**:
Hydrochloric Acid.....0,03 %
Detergent.....0,5 %

**pH** : 2,4 +/- 0,2 (T = 20°C)

**Resistivity** : 61 +/- 2 Ω (T = 20°C)

**Description**: Colorless aqueous solution.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument user manual.

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

Hematology ABX Devices (for in vitro diagnostic use)

# ABX ALphalyse

12/05/03
A95A00009-A

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Micros CRP | ✓ |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | ✓ |
| Pentra 120 Retic | ✓ |
| Pentra DX 120 | ✓ |
| Slide Preparation System | |

REF 0906004 (0,4L)
0902010 (1L)

REAGENT 0,4L or 1L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Lysing agent for white blood cell counting, and hemoglobin determination on ABX blood cell counters.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & expiration

**Storage conditions**: stored at 18°C (65°F) to 25°C (77°F) away from light. Product will degrade if exposed to air, keep cap / probe assembly securely tightened.

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual. This reagent is for professional *in-vitro* diagnostic use only.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & handling precautions

**Composition**:
Potassium Cyanide.....0,03 %
Quaternary Amonium Salt.....< 3 %

**pH**: 10 +/- 0,5 (T=20°C)

**Resistivity**: 213 +/- 10 Ω (T=20°C)

**Description**: aqueous solution, limpid.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested. The product can be absorbed through an open wound, or inhalation. Please refer to the MSDS associated with the reagent.

**Special precautions**: Avoid contact with acid and aqueous acid environment: extremely toxic cyanide acid vapour can be formed. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument User Manual

**Limitations**: see «Section: Specifications» in the instrument User Manual

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

Explore the future

HORIBA GROUP

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Lysebio

**Exclusive use:**

| | |
|---|---|
| Hematology ABX device | Exclusive |
| Micros 60 | ✓ |
| ABC Vet | |
| Micros CRP | |
| Pentra 60 | ✓ |
| Pentra 60 C+ | ✓ |
| Pentra 80 | ✓ |
| Pentra XL 80 | ✓ |
| Pentra 120 | ✓ |
| Pentra 120 Retic | ✓ |
| Pentra DX 120 | ✓ |
| Slide Preparation System | |

23/04/03
A95A00011-A

REF 0906013 (0,4L)
0906012 (1L)

REAGENT 0,4L or 1L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

This reagent is used on ABX blood cell counters to lyse red blood cells and determine hemoglobin concentration.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & expiration

**Storage conditions**: Stored at 15°C (59°F) to 30°C (86°F) away from light.

**Expiration date** : refer to «expiration date» reagent packaging label

## 3. Measurements, principles & results

**Directions for use**: see «Section: Maintenance & Troubleshooting / Reagent Location and connection» in the instrument User Manual.

**Measuring Principles** : see «Section: Description & technology» in the instrument User Manual.

**Results**: see «Section: Workflow» in the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & handling precautions

**Composition** :
Quarternary ammonium salt < 5%
Non ionic based surfactant < 3%

**pH**: 6,95 +/- 0,1 (T = 25°C)

**Resistivity**: 40 +/- 1 Ω

**Description**: Colorless, odourless.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent

**Specimen Collection and Mixing**: see «Section: Workflow» in the instrument User Manual

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual

**Safe Waste Disposal**: see «Section: Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

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HORIBA GROUP

Hematology ABX Devices (for in vitro diagnostic use)

# ABX Minoclair

**Exclusive use:**

| Hematology ABX device | Exclusive | Concentrated cleaning use |
|---|---|---|
| Minos | ✓ | |
| ABC Vet | | ✓ |
| Micros 60, Micros CRP | | ✓ |
| Pentra 60 | | ✓ |
| Pentra 60 C+ | | ✓ |
| Pentra 80 | | ✓ |
| Pentra XL 80 | | ✓ |
| Pentra 120 | | |
| Pentra 120 Retic | | |
| Pentra DX 120 | | |
| Slide Preparation System | | |

03/11/03
A95A00029-B

REF 0401005

REAGENT 0,5L

IVD CE

**ABX Diagnostics**
BP 7290 - 34187 Montpellier
cedex 4 - France

## 1. Functions

Cleaning and bleaching solution for ABX blood cell counters.

**Measurement procedure to be followed in using the device**: Principle of the method, specific analytical performance characteristics : see «Section: Specifications» in the instrument User Manual.

## 2. Conservation & Expiration

**Storage conditions**: Stored at 18°C (65°F) to 25°C (77°F).

**Expiration date**: refer to «expiration date» reagent packaging label.

## 3. Measurements, principles & results

**Directions for use**: see «Section: Reagent Location and connection» in the instrument User Manual.

**Measuring Principles** : see «Section: Technology» in the instrument User Manual.

**Results**: Refer to the instrument User Manual

**Performance data**: see «Section: Specifications» in the instrument User Manual.

Note: if performance changes, call your ABX Diagnostics representative.

## 4. Composition & Handling precautions

**Composition**:
Sodium hypochlorite: 9 % v/v at 13% of active chloride.
Sodium hydroxide: 0,26%

**pH**: 12,4 +/- 0,5 (T = 20°C)

**Resistivity**: Not available

**Description**: Yellowish liquid.

**Handling Precautions**: Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.

**Specimen Collection and Mixing**: see «Section: Specimen collection and Mixing» in the instrument User Manual.

## 5. Limitations & waste disposal

**Limitations**: see «Section: Specifications» in the instrument User Manual.

**Safe Waste Disposal**: Follow your laboratory's protocol when neutralizing and disposing of waste. Please refer to the MSDS associated with the reagent.

## 6. Concentrated cleaning exclusive use

Minoclair may also be used as disinfectant and cleaning product on ABX Blood cell counters: see «Section: Concentrated cleaning» in the user manual, on the following instruments: ABC vet, Micros 60, Micros CRP, Pentra 60, Pentra 60C+, Pentra 80, Pentra XL80.

S.A. au capital de 44.000.000Euros - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

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HORIBA GROUP

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